EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF WISCONSIN, THE COMMONWEALTH OF MASSACHUSETTS, THE COMMONWEALTH OF VIRGINIA, THE DISTRICT OF COLUMBIA, THE CITY OF CHICAGO, THE STATE OF CONNECTICUT, THE STATE OF COLORADO, THE STATE OF MARYLAND, THE STATE OF IOWA, and THE STATE WASHINGTON ex rel. CHARLES STRUNCK and LISA PRATTA, and Lisa Pratta individually	§	Docket No. 12-175 (BMS) FILED UNDER SEAL FOURTH AMENDED QUI TAM COMPLAINT
vs.	§	
Mallinckrodt ARD, Inc (formerly known as Questcor Pharmaceuticals, Inc., a California corporation), and Mallinckrodt, plc, an Irish public limited company Defendants.	§	

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RELATOR'S FOURTH AMENDED QUI TAM COMPLAINT

I. NARRATIVE SUMMARY

1. Plaintiffs/Relators hereby file this Fourth Amended Complaint[1] (Complaint) pursuant to Section 31 U.S.C. Title 3729 and 3730, under which a civil action may be brought for violations of 31 U.S.C. Section 3729 regarding false claims on behalf of the United States Government and the various States and municipalities listed herein under their own False Claims Act. This is an action to recover damages and civil penalties on behalf of the United States and various States or municipalities listed herein arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant Mallinckrodt ARD, Inc. (formerly known as Questcor Pharmaceuticals, Inc[2].), (Questcor) "a subsidiary of Mallinckrodt, plc[3] (Mallinckrodt). Questcor and Mallinckrodt are both referred to collectively as "Questcor" or ("Defendant(s)") and/or their agents,

[1] The Original Complaint was filed on January 17, 2012 and served on the United States on January 31, 2012. The First Amended Complaint was filed on or about August 8, 2013 and was also timely served on the United States. A Motion for leave to file the Second Amended Complaint was filed and granted on or about September 7, 2012. The Second Amended Complaint was timely served on the United States and the States named therein. A motion to file a Third Amended Complaint was granted and filed July 1, 2014 to include additional States which were inadvertently omitted in the Second Amended Complaint, being Washington, Maryland, Connecticut, Iowa and Maryland.

[2] The corporate name change was filed with the California Department of State on July 27, 2015 (Document ID# A0772903)

[3] On August 14, 2014, pursuant to the Agreement and Plan of Merger (the "Merger Agreement"), dated as of April 5, 2014, among Questcor Pharmaceuticals, Inc. ("Questcor"), Mallinckrodt, plc, an Irish public limited company ("Mallinckrodt") and Quincy Merger Sub, Inc. ("Merger Sub"), Merger Sub merged with and into Questcor, with Questcor being the surviving entity (the "Merger"). As a result of the Merger, Questcor became a wholly owned indirect subsidiary of Mallinckrodt.

employees or co-conspirators under the False Claims Act. Relator Pratta is also bringing individual causes of actions under the New Jersey Conscientious Employee Protection Act N. J. Stat. Ann. § 34:19-1 et. seq. ("CEPA") and New Jersey Law Against Discrimination N. J. Stat. Ann. N.J.S.A. 10:5-12 ("LAD")

2. Questcor manufactured, marketed and sold drugs for medicinal purposes, and its only FDA-approved product was H.P. Acthar Gel (repository corticotrophin injection). Acthar is a "specialty pharmaceutical. " It is neither sold in retail pharmacies, nor distributed through wholesalers to retail pharmacies. Instead, it is distributed through "specialty pharmacies." Distinguishing features of specialty pharmaceuticals like Acthar, beyond their high prices, is their alleged important therapeutic effects. Since the Merger Defendants have collectively continued to manufacture, market and sell H.P. Acthar Gel

3. Since at least 2007, Questcor has intentionally engaged in an illegal scheme to increase its sales and profits by engaging in the following illegal and fraudulent activities:

(i) in violation of the Anti-Kickback Statute[4] ("AKS") using valuable incentives, rewards and other forms of remuneration to induce healthcare providers to promote and prescribe H.P. Acthar Gel, in lieu of less-expensive therapies that are equally or more effective, for use by Government Health Care Program beneficiaries;

(ii) systematically promoting and marketing H.P. Acthar Gel for

[4] The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b)

unapproved, off label uses with regard to the dosing and administration of the drug using means and methods that are false, misleading and deceptive, and

(iii) systematically promoting and marketing H.P. Acthar using means and methods that are false, misleading and deceptive for unapproved off label uses to patients who have the progressive form of multiple sclerosis (MS) through a practice known as "pulse' therapy," even though it is only indicated for acute exacerbations or relapses. These types of MS patients are not indicated for H. P. Acthar Gel because they are not having acute relapses. Pulse therapy is a term used for monthly use or infusion of a drug on a prophylactic type basis. Even though Acthar is not indicated for this use, Questcor and their sales reps have been promoting this use to physicians and successfully getting it approved through a series of deceptive and misleading practices as described herein.

(iv) causing hundreds or thousands of false claims for reimbursement of H.P. Acthar Gel to be submitted to, and paid by, federal healthcare programs.

4. Defendant's conduct has cheated the federal government out of millions of dollars that should not have been paid, thereby enriching Defendant and subjecting patients to unapproved, unsafe and potentially ineffective uses of H.P. Acthar Gel.

5. These deceptive, false, and misleading methods included, inter alia, Defendant knowingly (i) disregarded federal laws and Food and Drug Administration ("FDA") regulations relating to off-label marketing and promotion; (ii) misrepresenting in it's promotion and marketing evidence concerning the efficacy

and safety of H.P. Acthar Gel; (iii) failing to disclose and submit to FDA all of its promotion, advertisements and marketing materials as required (iv) promoted H.P. Acthar Gel for uses that were neither effective nor safe; (v) utilized improper, false and misleading comparative marketing tactics, including unsubstantiated superiority claims; and (vi) improperly compensating, including giving free vials of H.P. Achtar Gel as an inducement, to healthcare professionals to induce them to promote and prescribe H.P. Acthar Gel. These illegal practices caused the submission of false claims. In so doing, Defendant has endeavored to undermine an important patient protection regulatory scheme that was developed over the course of almost fifty years.

6. The purpose of this Fourth Amended Qui Tam Complaint (herein "Complaint") is to (i) include additional evidence and facts that have been previously provided to the Government through voluntary supplemental disclosures since before and the filing of the Third Amended Complaint, (ii) reflect that the illegal practices that Questcor had been engaging in since 2007 have knowingly been continued since the merger and acquisition of Questcor by Mallinckrodt, and (iii) name and identify the Jane Doe relator, and include an individual causes of action for her (Lisa Pratta) under the New Jersey Conscientious Employee Protection Act N. J. Stat. Ann. § 34:19-1 et. seq. ("CEPA") and the New Jersey Law Against Discrimination N. J. Stat. Ann. N.J.S.A. 10:5-12 ("LAD").

II. PARTIES

A. Plaintiffs/Relators Charles W. Strunck and Lisa Pratta

7. Plaintiff/Relator Charles W. Strunck ("Relator Strunck") is a resident of the State of New York. He received a Bachelor of Science degree from Ramapo College of New Jersey in 1992. Relator Strunck was employed by Questcor from September 2010 until August 4, 2011 as a Multiple Sclerosis (MS) Sales Specialist with responsibility for sales in the States of New York and Connecticut.

8. Relator Strunck held the title of MS Sales Specialist throughout his tenure with Questcor. As such, his primary assigned role was to call on health care providers, including MS Centers and community-based neurologists, within his assigned region, and to encourage them to prescribe his H.P. Acthar Gel for their patients. Relator Strunck's compensation package was calculated as base compensation plus a bonus calculated based on total sales. In addition, Questcor from time to time would run "Special Incentive Plans" under which sales specialists could earn additional amounts based on sales volume.

9. Questcor terminated Relator Strunck's employment when injuries he suffered in a work-related motor vehicle accident (in which the other driver was at fault) ostensibly had a negative impact on his ability to do his job. Relator Strunck has initiated a worker's compensation claim as a result of the incident.

10. Relator Lisa Pratta (Relator Pratta) was an Achtar neurology specialists

with Questcor and thereafter Mallinckrodt from September 2010 until June 2017.

11. Relator Pratta's compensation package was calculated as base compensation plus a bonus calculated based on total sales. In addition, Questcor from time to time would run "Special Incentive Plans" under which sales specialists could earn additional amounts based on sales volume.

12. Relator Pratta promoted Acthar Gel (repository corticotropin injection) to Neurologists and Neuro-Ophthalmologists for MS relapses, optic neuritis., and neuromuscular indications such as dermatomyositis and polymyositis.

13. During her employment, Relator Pratta conducted Health Care Provider and patient programs, worked closely with the MS society and the MSAA and developed many Key Opinion Leader speakers.

14. Relator Pratta's employment was terminated as a result of her complaints and objections to supervisory personnel regarding a myriad of compliance issues as is more particularly described herein.

15. Relator Strunck and Relator Pratta are original sources of the Fraudulent Marketing Scheme allegations in this Complaint. The allegations in the Fraudulent Marketing Scheme are not based upon publicly disclosed information. Prior to filing this Complaint, Relators have provided the United States with Disclosure Statements as part of Relator's obligation to provide the government with material information prior to filing a Complaint in accordance with 31 U.S.C. § 3730(b)(2).

B. Defendant Questcor Pharmaceuticals, Inc.

16. Defendant Questcor Pharmaceuticals, Inc. is a California corporation headquartered in Anaheim, California and traded on the NASDAQ Exchange (Ticker Symbol: QCOR). It is a specialty pharmaceutical company focused on treating central nervous system disorders. On August 14, 2014, Questcor Pharmaceuticals, Inc. became a wholly owned indirect subsidiary of Mallinckrodt plc, an Irish public limited company ("Mallinckrodt"). Questcor changed it's name to Mallinckrodt ARD, Inc (formerly known as Questcor Pharmaceuticals, Inc., a California corporation.

17. Questcor, in or about January 2012, employed approximately 150 full-time employees, including a recently expanded Multiple Sclerosis ("MS") sales force of 77 sales representatives and 15 sale & managers. According to Questcor's 2010 Annual Report, the expansion of its MS sales force *"continues to allow [Questcor] to build upon positive growth trends in prescriptions of Acthar for the treatment of exacerbations associated with MS."* By 2014 the neurology sales force had grown to 87 sales representatives.

18. As of 2012, Questcor's National Sales Directors are Ed Hardin (East) and Doug Harmon (West), and they report to Eldon Mayer, who is the company's Vice President for Commercial Operations. The company's MS sales force is divided among 13 regions, each of which has its own Regional Manager. Relator Strunck was assigned to the Northeast Region and his Regional Manager was Ken Miller. Relator Pratta was also assigned to the Northeast Region.

19. Questcor also employs a team of medical science liaison ("MSLs") who report to the Director of Medical Science Liaisons, Nikki Mutschler. As of November 2010, Questcor employed ten MSLs. Sagar Shah is the MSL who was assigned to work with Relator Strunck.

20. At all times relevant to this Complaint, Defendant required its neurology sales specialists to promote and sell H.P. Acthar Gel to healthcare professionals throughout the United States.

21. Defendant expressly tied sales specialist compensation to sales growth, and it incentivized each sales specialist to increase sales growth irrespective of the rules against off label marketing. Indeed, the company's bonus structure - which paid hefty bonuses each month based on the number of prescriptions shipped - was designed to promote a "sell at all cost" mentality within the sales force.

22. Sales bonuses at Questcor are among the highest in the industry. In Q2 2011, the highest bonus paid to a sales specialist was $124,000 (Nick Brunetti, Denver), which included $75,000 in one month alone. Another sales specialist, Jason Ambrose, earned a $110,000 bonus during the same quarter, including $80,000 in one month alone. Questcor provides each sales specialist with a daily report tracking the productivity of all specialists in order to motivate them. This practice continued after the merger with Mallinckrodt.

23. Questcor required its sales specialists to promote and sell H.P. Acthar Gel to healthcare professionals throughout the United States. Questcor's sales

organization is relatively flat, ensuring that senior executives of the company are fully aware of the company's marketing strategies and results on a "real time" basis. In 2010, Questcor's net sales were approximately $115 million, reflecting significant year-over-year growth of approximately thirty percent.

24. Questcor reported to the U.S. Securities and Exchange Commission that net sales for Q2 2011 had increased approximately 62% over the same period in 2010, and that earnings per share had increased approximately 50% over the same period in 2010.

25. Substantially all of Questcor's sales are sales of H.P. Acthar Gel, and thus it is the linchpin of the company's financial success. Questcor stated in its Ql 2011 earnings call that net sales in the multiple sclerosis (MS) market were (then) approximately 60% of total net sales of the drug. The company repeatedly has told analysts and investors that it has experienced significant growth in scripts and revenues, and that it projects significant further growth in scripts and revenues, based largely on prescriptions for MS patients. Total net sales were $798.9 million for the year ended December 31, 2013 as compared to $509.3 million and $218.2 million for the years ended December 31, 2012 and 2011, respectively. Over 95% of net sales in each of these years were from H.P. Acthar Gel.

26. As described more fully herein, Questcor manufactures markets and sells H.P, Acthar Gel throughout the United States. During the relevant period,

Questcor marketed and sold substantial quantities of H.P. Acthar Gel in the United States.

27. H.P. Acthar Gel is paid or reimbursed by various Governmental Health Care Programs as set and described herein. According to Questcor's 2010 Annual Report, approximately 25% of the company's MS sales are to Medicare insureds. As a result of Questcor's actions described herein, the Government Health Care Programs have suffered financial harm.

C. The United States and State Plaintiffs

28. The United States of America is a real party in interest pursuant to the FCA, and specifically on behalf of several United States' agencies: the Department of Health and Human Services ("HHS"); its Centers for Medicare & Medicaid Services ("CMS"), as CMS administers the Medicare programs and the Food and Drug Administration ("FDA") which the Defendants' unlawful and fraudulent actions harmed.

29. The United States of America is a real party in interest pursuant to the FCA, and specifically on behalf of two United States' agencies: the Department of Health and Human Services ("HHS"), and particularly its Centers for Medicare & Medicaid Services ("CMS"), formerly the Health Care Financing Administration, as CMS administers the Medicare and Medicaid programs which the Defendants' unlawful and fraudulent actions harmed.

30. The States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas and Wisconsin, together with the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago are real parties in interest pursuant to each of their State FCAs, listed above, on behalf of each of their Medicaid agencies, which administer and fund each of said governmental entity's portion of Medicaid expenditures, as further described below, and which Defendants' unlawful and fraudulent actions harmed.

III. JURISDICTION

31. This action arises under the FCA, 31 U.S.C. §§3729 et seq., and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1345.

IV. VENUE

32. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and ©) since one or more of the Defendants transact business in this district and/or one or more of the acts at issue occurred in this district.

V. SUMMARY OF DEFENDANT'S ILLEGAL CONDUCT

A. The Purpose of The Fraudulent Marketing Scheme

33. It was the intentional plan and purpose of Questcor's scheme to illegally market H.P. Acthar Gel, beginning at least as early as 2007 and continuing to the

present as a subsidiary of Mallinckrodt, in order to increase sales of H.P. Acthar Gel by (i) providing valuable remunerations to induce and encourage physicians to promote and prescribe the drug for on- and off label uses; (ii) illegally promoting the drug (to both healthcare providers and patients), using false, deceptive and misleading methods and means, that are beyond the limit of its FDA approval with respect to the dosage and administration of the drug, causing the submission of false claims to the Government Health Care Programs and (iii) systematically promoting and marketing H.P. Acthar using means and methods that are false, misleading and deceptive for unapproved off label uses to patients who have the progressive form of MS through a practice known as "pulse" therapy, even though it is only indicated for acute exacerbations or relapses which caused the submission of false claims to the Government Health Care Programs.

34. Questcor intended that this scheme would cause greater quantities of H.P. Acthar Gel to be dispensed, including to Government Health Care Program beneficiaries, than otherwise would have been the case. Questcor intended that this would cause a higher dollar volume of reimbursements to be paid by Government Health Care Programs for the use of H.P. Acthar Gel than otherwise would have been the case, thereby enriching themselves. Indeed, one component of the scheme was an elaborate plan by Questcor to provide free, and often improper or fraudulent guidance and assistance to physicians to help them overcome barriers to reimbursement imposed by Government Health Care Programs. The underlying

purpose of the scheme was to maximize profits. These practices continued after the merger with Mallinckrodt.

35. Questcor's scheme was knowingly designed, at least in part, to enable it to sell H.P. Acthar Gel against a generic, substantially less expensive, steroid called Solu-Medrol (methylprednisolone sodium) that requires a shorter course of treatment for the treatment of exacerbations of MS than does H.P. Acthar Gel. These practices continued after the merger with Mallinckrodt.

36. The FDA-approved label[5] indicates a dosage and administration of a two to three week course of treatment with H.P. Acthar Gel, which in 2012 could cost as much as $150,000 per patient (assuming an 80-120 Unit daily dose over 21 days). In contrast, the cost for the recommended four-dose regime of Solu-Medrol, (the primary competitor of H.P. Acthar Gel) is estimated to be only $11,182 for in-patients, and less than $800 for out-patients. *See Robson, L.S. et al., Cost Analysis of methylprednisolone treatment of multiple sclerosis patients, CAN. J. NEUROL. Sci., 1998 Aug; 25(3): 222-9,*. More importantly, Solu-Medrol, unlike H.P. Achtar Gel, can properly be dosed in a five day treatment according to its "label" and FDA Approval.

[5] Copy of the FDA Approved label is attached hereto as Exhibit A. See Section "Dosage and Administration" which states that *"In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose."*

B. The Manner and Means of Executing The Scheme

37. Questcor intentionally employed a multi-tiered strategy to implement its Fraudulent Marketing Scheme. First, Questcor paid illegal kickbacks, in the form of bribes, free vials of H.P. Achtar, speaking and advisory fees, business consulting services, and other things of value, to physicians and their staff in order to induce them to promote and prescribe H.P. Acthar Gel for on- and off-label uses, and to reward those who already had done so.

38. Second, Questcor intentionally trained and utilized its sales force to employ false, deceptive and misleading information to probatively promote and sell H.P. Acthar Gel for indications and treatment regimens that are not approved by the U.S. Food and Drug Administration (FDA), as follows:

(A) first, as a dosage over five (5) days, instead of 2-3 weeks, so that it could compete with Solu-Medrol. In fact, Questcor concluded that the only way they could compete with Solu-Medrol was to off label market H.P. Achtar Gel with a "five day dosing" which is the "indication" that is part of the Solu-Medrol label. The off-label marketing scheme is directed to both physicians and MS patients.

(B) second, Questcor sales representatives are trained and encouraged to promote "pulse therapy" which means writing prescriptions for one (1) to three (3) vials to be used once a month. In order to enable this, sales representatives suggest that physicians need to diagnosis the patient with "active flare" or "acute flare" meaning that the patient is experiencing a "relapse," "attack" or "exacerbation."

This marketing scheme is targeted to those patients in a "progressive[6]" form of MS, i.e. referred to sometimes as a "continuous exacerbation."

39. Questcor did these things in reckless disregard of the unusually serious safety profile for H.P. Acthar Gel, as reflected in its FDA-approved label. Questcor has attempted to conceal and cover-up its payment of kickbacks and its illegal promotion of H.P. Acthar Gel by making false statements to the FDA and directing employees to conceal evidence by failing to disclose, inter alia, the full nature and extent of its advertising, promotional and marketing materials and plan. Questcor's unlawful promotion of H.P. Acthar Gel has involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of getting the false records or statements to bring about the federal government's payment of a false or fraudulent claim. In addition to the above and as described more fully herein, Questcor managers routinely ignore or encourage illegal promotional activities, and they certainly do not investigate and correct such misconduct as their Corporate Compliance Program purports to require. These practices continued after the merger with Mallinckrodt.

40. Questcor's conduct has had a material effect on the Government Health Care Programs decision to pay for H.P. Acthar Gel. Had these programs known that

[6] According to the FDA Approved Label, Acthar is only indicated for use for "acute" exacerbations. There are four classes of MS. Most patients have the form of relapsing-remitting MS. The other three types of MS are a "progressive" form, which means the patients are in a constant declining exacerbation. These three types of MS patients are not indicated for Acthar because they are not having acute relapses.

reimbursements were being made for H.P. Acthar Gel caused by Questcor's unlawful promotion, it would not have made such reimbursements. The above-described, and the specific details, facts and circumstances allege herein is referred to herein as the "Fraudulent Marketing Scheme." Questcor's perpetration of this Fraudulent Marketing Scheme is ongoing. These practices continued after the merger with Mallinckrodt.

VI. FEDERAL LAWS REGARDING REIMBURSEMENT AND FRAUD ENFORCEMENT

A. The Government Health Care Programs

41. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq., (hereinafter "Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services. Medicare is a health insurance program that provides for the payment of prescription drugs, hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program.

42. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was

designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

43. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. secs. 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

44. The federal government, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise.

45. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described above shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

B. The False Claims Act

46. The Federal FCA, 31 U.S.C. § 3729(a)(1)(A)[7] makes "knowingly[8]" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September on or after 29, 1999[9].

47. The Federal FCA, 31 U.S.C. § 3729(a)(1)(B) makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the

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[7] On May 22, 2009, the Fraud Enforcement and Recovery Act (FERA) was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered ceratin sections. Under FERA, effective 5/22/09 3729(a)(1) became 3729(a)(1)(A). Likewise, 3729(a)(2) became 3729(a)(1)(B) and 3729(a)(3) became 3729(a)(1)©. Since the allegations include a time period before and after 5/22/09, references are to be applicable sections

[8] "Knowingly" means the defendant (1) had actual knowledge that the claim is false; (2) acted with deliberate ignorance of the truth or falsity of the claims; or (3) acted with reckless disregard of the truth or false of the other claim. 31 U.S.C. § 3729(b)(1)(A)(1-3) and Section 2729(b)(1)(B).

[9] On November 2, 2015, President Obama signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990. The 2015 Act updates the process by which federal agencies adjust applicable civil monetary penalties for inflation to retain the deterrent effect of those penalties. The 2015 Act requires that not later than July 1, 2016, and not later than January 15 of every year thereafter, the head of each agency must, by regulation published in the Federal Register, adjust each CMP within its jurisdiction by the inflation adjustment described in the 2015 Act. For violations of the False Claims Act, the interim final rule minimum per-claim CMP's will increase to $10,781 from $5,500, and maximum per-claim CMPs will jump to $21,563 from $11,000. The increase takes effect August 1, 2015 and applies to violations after November 2, 2015.

Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

48. The Federal FCA, 31 U.S.C. sec. 3729(a)(1)© makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

49. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

C. The Anti-Kickback Statute

50. The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b), makes it illegal to:

> *offer*, receive, or solicit *any remuneration*, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order *to induce such person to purchase*, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of *any good, service, or item for which payment may be made in whole or in part under a Federal Health Care Program.*

VII. BACKGROUND OF THE REGULATORY FRAMEWORK

A. The Food and Drug Administration ("FDA") Regulatory System

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

51. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

52. To determine whether a drug is *"safe and effective,"* the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include *"full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use."* 21 U.S.C. § 355(b)(1)(A).

53. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *21 U.S.C. § 321.* The law requires that *"adequate and well controlled investigations"* be used to demonstrate a drug's safety and effectiveness. *21 U.S.C. § 355(d)(7).* The FDA approves a drug if there are *"adequate and well-controlled clinical trials"* that demonstrate a drug's safety and effectiveness for its *"intended conditions"* of use. *21 U.S.C. § 355(d)(5).* The

"intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *21 U.S.C. § 355(d)(1) & (2).* Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *37 Fed. Reg. 16,503 (1972).*

54. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by *"adequate and well-controlled clinical investigations"* has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. *21 C.F.R. § 314.26.*

55. The FDA also requires the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. In order to address this requirement, the FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 Guidance to the Industry, *"it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Guidance for Industry: Providing Clinical Evidence o Effectiveness for*

Human Drugs and Biological Products, May 1998. See, e.g., Final Decision on Benylin, 44 FR 51512, 518 (Aug. 31, 1979).

56. FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase *"adequate and well-controlled investigations"* was designed not only to describe the quality of the required data but also the *"quantum"* of required evidence. *See S. Rep. No. 1744, Part 2, 87thCong. 2d Sess. 6 (1962).* Nevertheless, FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, FDA has relied on pertinent information from other adequate and well-controlled studies of a drug, such as studies of other doses and regimens, of other dosage forms, in other stages of disease, in other populations, and of different end points, to support a single adequate and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

57. In other cases, FDA has relied on only a single, adequate and well-controlled efficacy study to support approval - generally only in cases in which a single multi center study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical

grounds. In section 115(a) of the Modernization Act, Congress amended section 505(d) of the Act to make it clear that the Agency may consider *"data from one adequate and well-controlled clinical investigation and confirmatory evidence"* to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

58. Cases in which the FDA has approved a drug on the basis of one clinical trial plus, confirmatory evidence are rare. They include instances of large, independently conducted multi center trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as *"adequate and well-controlled"* clinical trials needed to support FDA approval. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *21 C.F.R. § 201.57(3).*

2. FDA Regulations Prohibit Off Label Marketing Through False and Misleading Statements About a Drug's Use

59. FDA regulations restrict how drug companies may market and promote approved drugs. *See 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81.* Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. *21 U.S.C. §§ 331, 352.* Illegal "misbranding" can result in criminal penalties. *21 U.S.C. § 333.*

60. Drug companies such as Defendant must submit specimens of mailing pieces and any other labeling or advertising devised or used for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA–2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or *"advertisement"* for the product, which are also subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and in line with any written communications being submitted to FDA.

61. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular,

promotional materials may only make claims that are supported by *"substantial"* scientific evidence (according to strict scientific procedures) and they may not be false, deceptive or misleading. FDA oversight helps ensure a *"fair balance"* in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved *as well as the dosing regimen that is supported by the clinical trials* that were undertaken to establish safety and efficacy.

62. A drug company that wishes to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), ©; see also 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

63. The term "off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the. label, or

treating a different patient population, e.g., treating a child when the drug is approved to treat adults.

64. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education ("CM") courses and speaker programs, and drug company sponsored clinical trials.

65. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. *21 U.S.C. §§ 331, 352.* The

statute, *21 U.S.C. § 331(d)*, and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997).* The FDA *"interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."*

66. Any drug company's speech explaining one of its products is an *"advertisement"* for the product and is subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, as well as the FDA's *"fair balance"* requirement, described below. While a drug company may be entitled to certain First Amendment protection for truthful speech, see *U.S. v. Caronia*, 703 F.3d 149 (2d Cir.2012), off-label promotion that is false or misleading is not entitled to First Amendment protection. *Caronia,* at 166 n. 10. *See Cent. Hudson,* 447 U.S. at 566, 100 S. Ct. 2343. Under 21 U.S.C. § 331(a), a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA-approved drug, *e.g.,* making false or misleading statements about a drug.

67. Section 202.1(e)(6)(xi) provides that an advertisement may not use *"literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling."* See also 21 U.S.C. § 331(d) (prohibiting distribution of a drug for

non-approved uses); id. § 331(a) (prohibiting distribution of a misbranded drug); id. § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

68. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6) et seq. ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Thus, companies such as Questcor may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Government Programs, including Medicaid.

69. The regulations prohibit an advertisement that *"contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." 21 C.F.R. 202.1(e)(6)(iv).*

70. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *21 C.F.R. 202.1(e)(5) et seq.* A company violates this regulation if it presents *"false or misleading"* information about a drug's side effects or does not

"fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

71. Section 202.1(1)(2) broadly describes *"labeling"* of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

72. Section 201.56 requires labeling to be *"informative and accurate and neither promotional in tone nor false and misleading in any particular,"* to *"contain a summary of the essential scientific information needed for the safe and effective use of the drug,"* and prohibits *"implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."*

73. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

74. Section 99.101 et seq. lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer reviewed article that is considered *"scientifically sound"* by experts qualified to evaluate the safety or effectiveness of the drug involved. See 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be *"scientifically sound."* 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

75. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. 99.101(a)(4).

76. Additionally, off-label information may be disseminated only in response to an *"unsolicited request from a healthcare practitioner."* 21 U.S.C. § 360aaa-6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa(b) & ©; 360aaa-1.

77. The FDA does not generally regulate the exchange of scientific information, but when such information is provided by or on behalf of a drug company regarding one of the company's products, the information may be subject to the labeling and advertising provisions of the law and regulations. For example, while information provided at continuing medical education programs - such as medical conferences and professional gatherings intended to enhance physicians' knowledge and enable them to meet certain practice requirements generally is not subject to FDA regulation, it will be if the program has been funded and substantially influenced by a drug company.

78. In sum, the off label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body -- the FDA. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The FDA Has Limited Ability To Regulate Drug Maker Marketing and Promotion.

79. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off label uses. *See Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).*

80. DDMAC's effectiveness in regulating off label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre approved. FDA review of promotional materials occurs, if at all, only after the materials already have appeared in public. *See Woodcock Statement, supra.* Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the

promotional materials. *Id.* Sponsors occasionally are required to publicly correct product mis-impressions created by false, misleading, or unbalanced materials. *Id.*

81. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

82. The FDA's ineffectiveness in policing off-label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses (GAO 08-835), http://www.gao.gov/new.items/d08835.pdf.* Among the Report's findings: (i) FDA does not have separate oversight activities to specifically capture off-label promotion; (ii) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (iii) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (iv) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted material-for instance, discussions between doctors and sales representatives; (v) during calendar years 2003 through 2007, FDA issued 42 regulatory letters in

response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

B. The Orphan Drug Program

83. The Orphan Drug Act ("ODA") was enacted in 1983, and it provides various incentives for pharmaceutical companies to develop drugs for the treatment of rare diseases and conditions, defined by the ODA to include *"any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug."* 21 U.S.C. § 360bb(a)(2); 21 C.F.R. § 316.20(b)(8). These drugs are referred to as "orphan drugs," and incentives for orphan drug development include (i) tax credits of up to 50% for qualified clinical research expenses, see 26 U.S.C. § 45c; 26 C.F.R. § 1.28-1; (ii) a seven-year period of marketing exclusivity to the first sponsor who obtains marketing approval for a designated orphan drug, whether or not the drug is patentable, see 21 U.S.C. § 360cc; 21 C.F.R. § 316.31; and (iii) eligibility for research grants, see 21 U.S.C. § 360ee.

84. The orphan drug development program is administered by the FDA's Office of Orphan Products Development ("OOPD"). In order for a sponsor to obtain the orphan designation for a drug or biological product, an application must be submitted to the OOPD. *See 21 C.F.R. §§ 316.20 & 316.21.* The approval of an application is based upon the information submitted by the sponsor, and the

designations are indication-specific. *See 21 C.F.R. § 316.20(b)(3).* The approval of a drug for orphan drug status does not alter the standard regulatory requirements and procedures for obtaining marketing approval; however, historically, the approval time for orphan products as a group has been considerably shorter than the approval time for other drugs.

85. The tax credit provisions of the ODA are administered by the Internal Revenue Service. *26 C.F.R. § 1.28-1.* By reducing the costs to develop drugs for small patient populations, the credit allows companies to develop products that would otherwise be commercially unfeasible. The Orphan Drug Tax Credit applies to qualified clinical trial expenses that are incurred after the FDA has designated the drug as an "orphan."

86. The seven-year period of marketing exclusivity that is provided to orphan drugs is limited to the indication for which the orphan designation was approved. *See 21 C.F.R. §316.31.* By precluding competition, this period of exclusivity provides a powerful financial incentive to an orphan drug's sponsor. The FDA funds the development of orphan products through the "Orphan Products Grants Program," which is administered by the OOPD and provides funding for clinical research in rare diseases.

C. Prescription Drug Payments Under Federal Healthcare and Other Programs

87. Whether an FDA-approved drug is approved for a particular indication (i.e., use) determines whether a prescription for that use may be reimbursed under Medicaid and other federal healthcare programs.

1. The Medicare Program

88. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. Medicare serves approximately 43 million elderly and disabled Americans.

89. Federal statutes and regulations restrict the drugs and drug uses that the Federal Government will pay for through its funding of the Medicare program. Federal reimbursement for prescription drugs under the Medicare Prescription Drug benefit is limited to "covered outpatient drugs."

90. Covered outpatient drugs are drugs that are used for a "medically accepted indication." *42 U.S.C. § 1396x-8(k)(2)-(3).* A medically accepted indication, in turn, is a use that is listed in the labeling approved by the FDA, or that is included in one of three approved drug compendia: (i) the American Hospital Formulary Service Drug Information (AHFS-DI), (ii) the United Sates Pharmacopeia-Drug Information (or its successor publications); and (iii) the DRUGDEX Information System. *42 U.S.C. §§ 1396r-S(g)(1)(B)(i) and (k)(6).*

91. The first stage of the Medicare program, from May 2004 through December 2005 permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135 percent of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005.

92. Section 303© of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303© of the MMA amended Title XVIII of the Act by adding section 1847A, which established a new average sales price (ASP) drug payment system. Beginning January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the ASP methodology, and payment to the providers will be 106 percent of the ASP. There are exceptions to this general rule which are listed in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 17. The ASP methodology uses quarterly drug pricing data submitted to the CMS by drug manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis.

93. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies. Questcor has targeted Medicare Part D

beneficiaries for sales of H.P. Acthar Gel, including for off-label uses, by, among other things, assigning national account staff to ensure that H.P. Acthar Gel would be reimbursed. On occasion, Relator Strunck was required to work directly with Questcor's Associate Director for Specialty Distribution and Payer Relations, Jason Camp.

94. During the time period relevant to this Complaint, Questcor promoted off label uses of H.P. Acthar Gel that were not eligible for reimbursement from Medicare because the dosage that Questcor encouraged healthcare providers to prescribe was neither listed in the FDA approved labeling nor included in any of the drug compendia specified by the statute.

VIII. BACKGROUND AND APPROVAL OF H.P. ACTHAR GEL

95. Acthar (corticotrophin) was a brand-name drug that was developed by the company now known as Sanofi-Aventis, and that was first approved by the U.S. Food and Drug Administration (FDA) in 1950. H.P. Acthar Gel is a different, albeit related, drug that also was developed by Sanofi-Aventis, and that was first approved by the FDA in 1952. Questcor acquired the rights to both Acthar and H.P. Acthar Gel in 2001.

96. H.P. Acthar Gel is an injectable drug. It is a 39-amino-acid peptide natural form of adrenocorticotropic hormone (ACTH). It works by stimulating the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a few other

weakly androgenic substances. Thus, H.P. Acthar Gel is an adrenocorticotropic hormone (ACTH) analogue.

97. Upon acquiring Acthar and H.P. Acthar Gel from Sanofi-Aventis in 2001, Questcor applied for "Orphan Drug" designation for H.P. Acthar Gel for the treatment of Infantile Spasms (a very rare medical condition that affects fewer than 20,000 infants in the United States). That application was approved on May 21, 2003, but with an exclusivity start date of October 15, 2010 (the date the FDA approved H.P. Acthar Gel for the treatment of Infantile Spasms). Although orphan drug status is limited to the indication for which it was granted (Infantile Spasms), the marketing exclusivity afforded by orphan drug status (i.e., the seven-year period during which the FDA will not approve any other ACTH formulation for the treatment of Infantile Spasms) has provided Questcor with significant pricing protection for H.P.Acthar Gel, generally.

A. FDA Approval of H.P. Acthar Gel

98. The FDA approved H.P. Acthar Gel on April 29, 1952 for multiple indications, and the approval was expanded to include multiple sclerosis (MS) in 1972. In 2010, the FDA provided additional approval for the treatment of infantile spasms in pediatric patients (IS). Thus, today, H.P. Acthar Gel is approved by the FDA for the following indications:

(i) as monotherapy for the treatment of IS in infants and children under two years of age;

(ii) for the treatment of acute exacerbations of MS in adults;

(iii) as adjunctive therapy for short-term administration in various rheumatic disorders;

(iv) during an exacerbation or as maintenance therapy in cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis) (two collagen diseases);

(v) for severe erythema multiforme or Stevens-Johnson syndrome (two dermatologic diseases);

(vi) for serum sickness;

(vii) for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa;

(viii) for symptomatic sarcoidosis; and

(ix) to induce a dieresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

However, substantially all of Questcor's net sales are generated from just three of those indications: (i) acute exacerbations of MS in adults; (ii) nephrotic syndrome (NS); and (iii) infantile spasms.

99. H.P. Acthar Gel is a dangerous drug with wide-ranging and potentially life threatening adverse effects. Thus, its FDA-approved label specifically warns that patients taking H.P. Acthar Gel may suffer:

(i) increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections, although signs and symptoms of infection may be masked;

(ii) adrenal insufficiency

(iii) Cushing's Syndrome

(iv) elevated blood pressure;

(v) masking of symptoms of other underlying diseases and disorders;

(vi) gastrointestinal perforation and bleeding;

(vii) behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis;

(viii) comorbid diseases, such that symptoms of diabetes and myasthenia gravis may be worsened;

(ix) ophthalmic effects, such as cataracts, infections and glaucoma;

(x) loss of endogenous activity

(xi) enhanced hypothyroidism or liver cirrhosis for patients already suffering from those conditions;

(xii) negative effects on pediatric growth and physical development;

(xiii) decrease in bone density; and

(xiv) potential fetal harm in patients who are pregnant.

100. Additionally, the FDA-approved label warns that patients taking immuno suppressive doses of H.P. Acthar Gel should not be administered live or attenuated vaccines,

101. In view of H.P. Acthar Gel's unusual safety profile, the FDA took the additional, non-standard step when it approved H.P. Acthar Gel for the treatment of IS of also approving a Risk Evaluation and Mitigation Strategy (RAMS) that requires Questcor to distribute an approved Medication Guide with each prescription, and also to submit RAMS Assessments to the FDA at periodic intervals following approval of the RAMS. The approved Medication Guide elaborates on the serious and significant side effects associated with H.P, Acthar Gel.

B. Compendium Approval of H.P. Acthar Gel

102. Congress has adopted a compendia-based system for determining appropriate reimbursements for off-label uses of a "covered outpatient drug." *See Social Security Act §§ 1927(g)(1)(B)(i) and (k)(6).* The statute permits reimbursements for drug uses that *"(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."* The only way a prescription for an off-label use could be reimbursed under Medicare or the other Government Programs is if the particular off-label use was has been recommended by one of the compendia identified in the statute, Social Security Act, such a recommendation qualifying the use as a "medically accepted indication." *Id.*

103. There are only three compendia supported uses for H.P. Acthar Gel beyond its FDA-approved label:

i. DRUGDEX supports the use of H.P. Acthar Gel for the treatment of adrenal insufficiency in adult and pediatric patients. This is a Class Ha recommendation.

ii. DRUGDEX supports the use of H.P. Acthar Gel for the treatment of gout in adult patients. This is a Class 11b recommendation.

iii. The AHFS compendium supports the use of H.P. Acthar Gel for the treatment of active, moderate to severe, Crohn's Disease.

C. Questcor's Predatory Pricing of H.P. Acthar Gel

1. Questcor Used Orphan Drug Status To Dramatically Increase Price

104. In August 2007, in anticipation of receiving FDA approval of an indication for H.P. Acthar Gel to treat infantile spasms, Questcor announced a new business model and pricing strategy for H.P. Acthar Gel. This new pricing strategy increased the cost of H.P. Acthar Gel from approximately $1,600 per vial to approximately $23,000 per vial. This increased the cost of a typical course of treatment for Infantile Spasms from approximately $6,400 to $92,000, and it increased the cost of the FDA-recommended course of treatment for acute exacerbations of MS from approximately $7,000 to $100,000 or more.

105. Questcor was able to make this change because orphan drug status precluded the FDA from approving another ACTH formulation for seven years,

unless the other formulation were demonstrated to be clinically superior to H.P. Acthar Gel - a very high bar. As a practical matter, this precluded the FDA from approving another ACTH formulation for any purpose, thus providing Questcor with market exclusivity.

106. Market exclusivity provided substantial protection against downward pricing pressure from similar drugs, because the FDA could not approve any similar drugs. However, it created significant pressure for Questcor to distinguish H.P. Acthar Gel from the much cheaper and widely-preferred Solu-Medrol for acute exacerbations of MS, which remained the predominant intended use of H.P. Acthar Gel. (Solu-Medrol is not precluded by H.P. Acthar Gel's orphan drug status because it is not a formulation of ACTH and is not indicated for the treatment of infantile spasms.) This pricing pressure, combined with the fact that Solu-Medrol is approved for a substantially shorter course of treatment than H.P. Acthar Gel for acute exacerbations of MS, provided the impetus for Questcor's Fraudulent Marketing Scheme, described infra.

107. The implementation of this new pricing strategy also included a change in the method of distribution for H.P. Acthar Gel from multiple distributors to a single specialty distributor, CuraScript Specialty Distribution, Inc. ("CuraScript"). In August 2007 Questcor elected to stop selling Acthar to wholesalers and its sole distributor of the drug became CuraScript. Simultaneously, the average wholesale price of the same 5 ml vial increased to $29,086.25. In summary, Questcor sells H. P. Acthar Gel at a discount from its list price to

CuraScript, which then resells the H.P. Acthar Gel primarily to approximately twelve specialty pharmacies and to children's hospitals.

108. Effective January 1, 2011, Questcor's price to sell H.P. Acthar Gel to CuraScript was $24,195 per vial. Each vial is a 5ML multi-dose vial that includes 80 units/ML of the drug. As discussed below, that is enough drug for a five-day course of treatment. The cost has continued to increase dramatically and is now over $38,000.00 per vial.

109. At all relevant times, Questcor has known that H.P. Acthar Gel is being paid for or reimbursed by Government Programs, including Medicare Part D, TRICARE and the Veterans Administration - all of which generate net sales for the company. Although Questcor has since January 1, 2011 paid a Medicare rebate for H.P. Acthar Gel under the Patient Protection and Affordable Care Act of 2010 and the Healthcare and Education Affordability Reconciliation Act of 2010, the company estimates that rebate is less than ten percent of the price of the drug.

2. Questcor Implemented a Fraudulent Marketing Scheme to Increase Sales and Reimbursements of H.P. Acthar Gel.

110. When Questcor implemented its predatory price increase for H.P. Acthar Gel in 2007, Questcor understood that the primary clinical use for the drug was for the treatment of acute exacerbations of MS, and that financial success hinged on the company's ability to persuade physicians to prescribe the drug in lieu of its primary competitor drug, Solu-Medrol.

111. Questcor knew it faced a daunting task because (i) physicians considered Solu -Medrol to be the *"gold standard"* for acute exacerbations of MS; (ii) Solu-Medrol required only a five-day course of treatment, as opposed to the two to three week course approved indication by the FDA for H.P. Acthar Gel; and (iii) at approximately $1,200, a single course of treatment with Solu-Medrol was far less expensive than the $100,000 or more that a full, FDA-recommended two to three week course of treatment with H.P. Acthar Gel would cost. Questcor's Fraudulent Marketing Scheme was designed and intended to meet this challenge.

112. Beginning at least as early as 2007, Questcor designed its Fraudulent Marketing Scheme to increase sales of H.P. Acthar Gel by (i) promoting H.P. Acthar Gel for unapproved doses and indications in order to more effectively compete against Solu-Medrol for treatment of acute exacerbations of MS; and (ii) inducing doctors to promote and prescribe H.P. Acthar Gel by providing them with things of value.

113. Questcor knows, or it has been reasonably foreseeable to Questcor, that its promotion of H.P. Acthar Gel leads to the submission by physicians, specialty pharmacies and government-funded health plans of prescriptions that are ineligible for payment by Government Programs.

114. By way of example, on June 3, 2011, Regional Manager Ken Miller circulated an email to his sales specialists that recommended they follow certain enumerated strategies (developed by sales specialist Allison Polich) for persuading medical practices to prescribe H.P. Acthar Gel for their patients who are Medicare

beneficiaries. As a result by way of example, during the third quarter of 2011, Questcor shipped 2,910 vials of Acthar, up 54% compared to 1,890 vials in the year ago quarter.

115. When Questcor initially decided to employ the illegal practices described herein, it knew or should have known that physicians, specialty pharmacies and federally-funded health programs would routinely and necessarily file claims with Government Programs for reimbursement for H.P. Acthar Gel prescriptions. But for Questcor's illegal promotion, these prescriptions for H.P. Acthar Gel would not have been written, or they would not have been paid or reimbursed by Government Programs. As a result, Questcor has caused, and continues to cause, the submission of false claims to Government Programs for reimbursement of H.P. Acthar Gel. Questcor has been the beneficiary of these false claims for reimbursement of H.P. Acthar Gel prescriptions.

IX. Questcor Illegally Promotes and Markets H.P. Acthar Gel for Off-Label Use.

A. Questcor Promotes H.P. Acthar Gel For Unapproved Five Day Dosage Through False, Misleading and Deceptive Practices.

116. The FDA-approved label for H.P. Acthar Gel recommends a two to three week course of treatment for acute exacerbations of MS because that is the only protocol for which there is any reliable scientific data demonstrating both efficacy and relative safety.

117. However, Questcor recognized as early as 2007 that promoting H.P. Acthar Gel for a two to three week course of treatment would be a non-starter for

most physicians, since Solu-Medrol was equally effective, much less expensive, and required only a five-day course of treatment.

118. Thus, the starting point of Questcor's promotional strategy was a decision to proactively promote and market H.P. Acthar Gel for a one week (five-day) course of treatment instead of the two to three week course designated in its FDA-approved label, Indeed, Questcor's own slide-decks for its March 2011 and September 2011 Investor Relations Conferences described the MS dosing period as "1-2 weeks." See Exhibit B attached hereto, NASDAQ: QCOR, March 2011, page 10.

119. Questcor made this decision, and implemented this sales strategy, despite the fact that the only data regarding the safety and efficacy of a five-day course of treatment is anecdotal evidence of a Questcor-sponsored investigation conducted by Dr. Stanley A. Brod that has not been published and did not follow necessary clinical guidelines. (hereafter, the "Brod Protocol"). A copy of the Brod Protocol is attached hereto as Exhibit C. Not coincidentally, Dr. Brod is Questcor's most highly paid promotional speaker. Moreover, Questcor failed to disclose use of the Brod Protocol to the FDA as required by 21 C.F.R. § 314.81(b)(3)(i) and the submission of FDA Form 2253. Questcor did this knowing full well the significant safety risks that are associated with taking H.P. Achtar Gel (see ¶¶ 99 - 101)

120. During initial sales training in 2010, during national sales meetings, and during field training with Regional Managers, Questcor and then Mallinckrodt after the merger, and to the present consistently tells its sales specialists that they should promote H.P. Acthar Gel for a five-day course of treatment (without even

mentioning the broader language in the drug's FDA-approved label) because that was the only way they could compete effectively against Solu-Medrol. This was referred to as the "Brod Plan." Attached hereto as Exhibit D is a copy of a Power Point presentation used by Questcor for training with its sales force. On page 5 of the Presentation under the caption "The New MS Plan" it, inter alia, directs the sales force to use the *"Brod Plan,"* e.g., market the H.P Achtar Gel as a five day dosing regimen. Questcor failed to disclose use of the Plan to the FDA as required by 21 C.F.R. § 314.81(b)(3)(I) and the submission of FDA Form 2253.

121. On April 20, 2011, Relator Strunck's immediate supervisor, Regional Manager Ken Miller, specifically told him both verbally and via email that he should speak with co-relator Lisa Pratta, a successful sales specialist in New Jersey, to learn how she was promoting the five-day Brod protocol so that he could incorporate her techniques into his own sales process.

122. Questcor training of sales representatives to promote and market the five day dosing continued through 2013 by using Power Point slides[10] used for training speakers. In particular, please note slide #5 regarding "Achtar Dosing in MS" which, after stating the label dosing, continues with the following guidance:

- *"Dosage should be individualized according to the medical condition of each patient"*

[10] See Attached Exhibit E - Achtar Speaker Training, see slide 5

- *"Dosing frequency should be determined according to the severity of the disease and the initial response of the patient"*

There is an important and critical distinction between this language and the Label. The FDA Label[11], under DOSAGE AND ADMINISTRATION states as follows:

. . . .

- **In the treatment of acute exacerbations of multiple sclerosis,** daily intramuscular or subcutaneous doses of 80 -120 units for 2 - 3 weeks may be administered. It may be necessary to taper the dose. (2.2).

- **In the treatment of other disorders and diseases,** dosing will need to be *individualized depending on the disease under treatment and the medical condition of the patient.* It may be necessary to taper the dose (2.3)

Questcor failed to disclose use of these slides to the FDA as required by 21 C.F.R. § 314.81(b)(3)(i) and the submission of FDA Form 2253.

123. By comparing the dosing in MS training slide to the dosing guidelines on the Label for MS and *"other disorders and diseases"*, it is clear that Questcor is training speakers to promote dosing for MS contrary to the label. Specifically, Questcor has taken the "Dosing and Administration" labeling for *"other disorders and diseases"* [see above] and transposed it for training purposes into the labeling

[11] A copy of the approved FDA Label is included herein at the back of Exhibit A

for *"treatment of acute exacerbations of multiple sclerosis."* This can only be interpreted as a direct promotional statement contrary to the labeling for treatment of acute exacerbations of multiple sclerosis. It is clear that they are attempting to take advantage of the non-specific dosing regimen for that is part of the label for *"other disorders and diseases"* and make it part of the dosing for *"treatment of acute exacerbations of multiple sclerosis."*

124. Questcor also directly promoted off-label five day dosing through presentation of misleading comparative studies performed by Questcor employees. Attached hereto as Exhibit F is an "in house" study used as a sales tool entitled *"A Comparison of the Safety/Tolerability and Pharmacodynamics of Achtar Gel and Methylprednisolone With Regimens Utilized For The Treatment of MS Exacerbations"* (herein, the "Study" or "Marketing Brochure"). This Marketing Brochure is a clear and brazen example of illegal off-label promotion that has caused the submission of false claims in the following manner:

A. In the INTRODUCTION section, Questcor states that Achtar and intravenous methylprednisolone (IVMP) *"are both utilized to treat multiple sclerosis (MS)."* While this may be true for IVMP, H.P. Achtar Gel is only indicated for "acute exacerbations." This is clearly an attempt to promote H. P. Achtar Gel for the progressive form of MS through "pulse therapy."

B. Also, in the INTRODUCTION section, Questcor represents that the dosing regimen used (5 days) in the Study, is a *"dosing regimen for both of the drugs that have been commonly employed for treatment of MS exacerbations."*

While this may be true for IVMP, H. P. Achtar Gel is only indicated for a dosing regimen of 2-3 weeks. If a dosing regimen of 5 days has become *"commonly employed"* for Achtar it can only be attributed to Questcor's massive off label marketing promotion.

C. The Study clearly uses a dosing regimen of 5 days without any of the safeguards required by the FDA for a clinically sound study. According to the FDA, the statutory requirement that a drug's effectiveness be demonstrated by *"adequate and well-controlled clinical investigations"* has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. *21 C.F.R. § 314.26.* The Study outlined in this Marketing Brochure fails to meet this standard for multiple reasons as follows:

1. It has not been accepted for publication by a reputable neurology journal.

2. It contains a very small sampling of patients which would not be acceptable to the FDA because it would not qualify to show statistical significance.

3. The poster only deals with the measurement of cortisol levels of patients after they had both Acthar and solu-medrol even though Questcor management knows that it is not a measure of efficacy between the two drugs. It is

solely intended for the sales force to use it as an example to sell 5 day dosing and also to make a comparison of H. P. Acthar Gel to IVMP in efficacy and side effects.

4. A clinically sound study would have had at least 100 patients and would also be a double blind study which means the groups did not know which drug they were taking. Here the patients knew which medication they were taking.

5. The comparison study set forth and described in the Marketing Brochure was done by Questcor employees and is based on a dosing regimen of 80 U/ml for 5 days.

Moreover, Questcor failed to disclose use of the Marketing Brochure to the FDA as required by 21 C.F.R. § 314.81(b)(3)(I) and the submission of FDA Form 2253.

B. Questcor Promotes H.P. Acthar Gel Five Day Dosing For Unapproved Indication of "Progressive" MS Through Pulse Therapy

125. According to the FDA Approved Label, H. P. Acthar Gel is only indicated for use for"acute" exacerbations of MS. There are four classes of MS. Most patients have the form of relapsing-remitting MS. The other three types of MS are a progressive form, which means the patients are in a constant declining exacerbation. These three types of MS patients are not indicated for Acthar because they are not having acute relapses.

126. Neurologists have used "pulse therapy" on their progressive patients with solu medrol for many years. Pulse therapy is a term used for monthly use or infusion of a drug on a prophylactic type basis. Even though H. P. Acthar Gel is not indicated for this use and condition, Questcor and their sales reps have been promoting this use to physicians.

127. Questcor is promoting the 5 day course of therapy (1 vial) to be used on these "progressive" MS patients once a month. Because insurance companies, Medicaid and Medicare will not pay for an off label use of H. P. Acthar Gel, sales representative have been and are instructed to *"pre-populate"* on the written Referral Form that the patient is in an "acute" exacerbation. This is done by indicating on the left hand side of referral on the bottom the ICD-9 diagnosis code "340" which means "acute." (See Exhibit H)

128. An example of this practice is the Referral Form (attached hereto as Exhibit H) for Amos Katz, MD. This was done by Joe Citkowski, Relator Pratta's KOL (Key Opinion Leader) who told Pratta that she *"should fill this in on the forms for them."* Citkowski also did this for Dr. Terrance MacAlarney and Dr. Caren Marks who are part of the same practice as Dr. Amos Katz. The form has been pre-populated with *"80 units once/day for 5 consecutive days."* This was done and given to Dr. Katz's nurse (Rita) so that she would have a "model form" to follow. Citkowski is a KOL Sales Representative and Citkowski advised Pratta that this practice is being repeated elsewhere by other representatives and is not an isolated instance. This was done by Citkowski sometime between June 11, 2013 and August

2, 2013 when Relator Pratta learned about it at a lunch meeting with Dr. Katz and Citkowski.

129. This practice is continuing but Questcor has changed the Referral Form. A copy of the new Form is attached as Exhibit I. On page 3 of the new form, there is a "DIAGNOSIS AND MEDICAL INFORMATION" section. One of the questions is related to the type of MS the patient has as follows:

. . .

❑ **Multiple Sclerosis**

Is Achtar to be used to treat an acute exacerbation ❑ **yes** ❑ **no**

. . .

Joe Citkowski, Lisa's KOL (Key Opinion Leader), who has been pre-filling the "acute" designation of "#340" on the old form, advised Pratta on March 10, 2014 that, with respect to the new referral form, he is *"going to pre fill in the form"* and *"check off the box for acute for his other offices."*

130. In the Fall of 2016, Relator Pratta was assigned to a new reimbursement manager. His name is Jonathan Rosser, who joined Defendant in early 2015. Rosser handles all divisions: Neurology, Rheumatology, Pulmonology, and Nephrology. Mr. Rosser told Relator Pratta on the phone on October 28, 2016 that representatives from all divisions are *filling out the referral forms* [i.e. forms referred to above] *and are writing letters of medical necessity for their physicians.*

131. Questcor sales representatives were being encouraged to promote "pulse therapy" which means writing a prescription for three (3) vials to be used once a

month. One of the ways Defendant enabled this was to have sales representatives suggest that physicians need to diagnosis the patient with "active flow." Stacy Clancy, at the direction of Mike Zorzy, and Corey Prado, at the direction of Ken Miller are examples of where Relator is aware this is occurring. At the end of the three month period, a new prescription is written for three vials for another three months.

132. As a follow up to this, Christine Traficant, who is a sales representative in Relator Pratta's region, told her at the AAN meeting in San Diego on March 13, 2013, that the new pulse therapy dosing promotion[12] went over *"really well at the meeting."* Specifically, one of her physicians, (Dr. Charles) who was there stated that he was going to begin to use Acthar for pulse therapy. John Stabile, her manager said that *"Christine was probably now be seeing plenty of "pulse" business."* A copy of the promotion presented at the AAN Meeting in San Diego is attached hereto as Exhibit J. The Abstract suggested a benefit for H.P. Achtar Gel using monthly pulse therapy but acknowledges that "*further studies, including randomized controlled trials are needed to validate the findings."*

133. Questcor sales representatives are also telling the neurologists to write for one vial and add three refills, so it does not appear as a pulse therapy use for the patient. Questcor was paying their sales reps for these monthly referrals for the pulse therapy use for the same patient, but in the February 2013 National Sales meeting, announced that reps will only be paid for one referral each quarter so it does not look like they are paying reps bonus for "off label" use. Stacy Clancy, a neurology sales

[12] See Exhibit J. Abstract released at AAN Meeting on March 10, 2013.

representative, in a conversation that occurred on or about April 12, 2013 learned from Nick Brunetti (Questcor's Number 1 Sales Rep for Acthar MS) that *"all of his business was for monthly pulse therapy."*

134. KOL Sales Representative Joe Citkowski is one of the primary reps who pursues this strategy and gets the majority of the credit for them. Some of the Physician/Sales Representatives include:

Physician	Sales Representative
Ruth Brobst MD	Stacy Clancy
Susan A. Gaulthier MD NY,	James Worsham
Derek Smith MD	Ted Medru
Tim Vartanian MD NY	James Worsham
Johnathan Howard MD	James Worsham
Robert Knobler MD	Stacey Clancy
Jason Silverstein MD	Bob Bobeck

C. Defendant Is Promoting Five Day Dosing of Achtar as "indicated" for "First Line Use."

135. Achtar sales representatives are now being directed to market and promote Achtar as a "first line" use despite the fact that all Government Health Care Programs (and others) have consistently required prior to authorization and certification that the MS patient is (i) being treated with a relapsing remitting multiple sclerosis agent (e.g., Avonex, Betaseron, Copaxone, Gilenya) *AND* there is a failure or clinically significant adverse effects to corticosteroid therapy for acute exacerbations of multiple sclerosis.

136. There is no published, peer reviewed article, material, finding or study considered *"scientifically sound"* by experts that supports the use of H. P. Achtar Gel as a first line use for MS. This renders these prescriptions as "off-label" and "medically unnecessary."

137. Specifically, as part of it's new business plan instituted in the Fall of 2016, sales representatives are being directed to complete physician profile sheets (PPS) that were designed and sent out by the VP of Neurology, Kyle Jennings. This practice is further confirmed by the individual Physician profiles that each representative is asked to complete for their respective physicians. See Exhibit K[13].

138. On page 5 of the PPS (Exhibit K), the sales representative is directed to answer the following question:

Does the physician understand ACHTAR is indicated first line in relapse?

This is being used as a follow up the sales division to make sure the message about first line use is being conveyed.

D. Questcor Misused Medical Information Request Forms (MIRFs) As a Way of Promoting and Marketing the Five Day Dosing and Pulse Therapy

139. Another way in which Questcor promoted this off-label dosage of H.P. Acthar Gel was through its use of Medical Information Request Forms ("MIRFs"). A

[13] The PPS attached hereto is one from Taiman Zaman, MD, a physician that Relator Lisa Pratta calls on. As you will note, Pratta responded by stating *"Achtar is not first line"* and advised her superiors in writing of this on December 6, 2016. In late January she was advised that her territory is being restructured and is being terminated. However, she has been informed that sales representatives are being directed to promote Achtar in this manner and the PPS is being used to corroborate that it is being done.

copy of the MIRF is attached hereto as Exhibit G. Relator Strunck was specifically directed by Ed Hardin that he (and all other sales specialists) should proactively encourage every doctor he called on to sign a MIRF requesting information on the five-day course of treatment with H.P. Acthar Gel, whether or not the doctor initiated any discussion of the subject. Defendant used the MIRF as a pretext and for "cover" in that the sales force had already been directed to and in fact, had already discussed the "Brod Plan."

140. Thus, at the direction of management and as a matter of course, Sales Representatives prepared and submitted MIRFs requesting such information for every doctor they called on. Relators then received copies of the responsive materials that Questcor sent to the "requesting" doctors. Those materials explicitly promoted the so-called five-day "Brod Protocol" with H.P. Acthar Gel as being equally as effective as therapy with intravenous Solu Medrol, even though there was no clinically rigorous data to support that claim.

141. Several doctors, including Drs. Leonard Pickard and Mustafa Kahn (Kingston, NY), challenged the Brod Protocol as being thinly supported and not persuasive, and they refused to prescribe H.P. Acthar Gel at all. But others were persuaded by this misleading promotion. Among the doctors who started prescribing the five-day course of therapy with H.P. Acthar Gel upon receipt of a "response" to one of these MIRFs were Dr. Alice Rusk (Stamford/Greenwich, CT) and Dr. Nilay Shah (Mt. Kisco, NY).

E. Questcor Illegally Uses Medical Science Liaisons to Promote Off Label Uses of H.P. Acthar Gel.

142. Another tactic employed by Questcor to promote H.P. Acthar Gel off-label is to use its Medical Science Liaisons ("MSLs") as an end-run around sales representatives' duty to lawfully promote the drug. Questcor's use of MSLs in this manner is a way for the company to make the unlawful promotional activities for H.P. Acthar Gel appear lawful. *See e.g. 21 C.F.R. 99.101 et seq.*

143. Medical Science Liaisons are supposed to talk with physicians only about science-to-science issues, and only when those discussions are initiated by the physician. Their primary role is to engage in non-promotional medical activities, and they are not supposed to engage in product promotion. Thus, a sales representative is not permitted to use an MSL as a conduit through which to initiate and pursue off-label promotional activities with physicians.

144. The law notwithstanding, Questcor erects no wall between its medical and sales staffs, and actively encourages its MSLs to probatively participate in promotional activities. Medical Science Liaisons routinely accompany Questcor sales representatives on their sales calls.

145. Questcor encourages its sales representatives to probatively partner with MSLs to increase H.P. Acthar Gel sales growth. Commonly, the sales representative will initiate an off label discussion, and then the MSL will complete the discussion. On other occasions, sales representatives ask their MSL colleagues to contact physicians who are reluctant to prescribe H.P. Acthar Gel for off-label uses in order to attempt to

overcome that reluctance whether or not the physician initiated the off label discussion or requested further information. Again, Questcor ignores that MSLs are not permitted to engage in promotional activities.

F. Five Day Course of Treatment Was Ineffective and Harmful to Patients

146. Many physicians have rightly rejected Questcor's efforts because the 5-day protocol is not supported by any credible evidence, and because experimenting with it cannot be justified in light of its cost and potential for patient harm. However, many physicians have been persuaded to switch from Solu-Medrol to a 5-day course of treatment with H.P. Acthar Gel - in large measure due to the valuable inducements provided to them by Questcor, as described herein.

147. In Relator Strunck's experience, approximately half the doctors he persuaded to prescribe H.P. Acthar Gel for a five-day course of treatment had to order repeat prescriptions in as few as two to three months due to patient relapse, even though patients treated with Solu-Medrol typically relapse only after twelve to eighteen months. Relator Strunck knows this issue was widespread, because it was regularly was discussed during regional sales team conference calls. In Relator Pratta's experience, she experienced the same reactions from patients who doctors used the 5 day course of treatment.

148. Questcor's decision to promote H.P. Acthar Gel only for a five-day course of treatment came at the detriment of patients and patient safety. The issue was routinely discussed during regional sales calls and national sales meeting, Questcor knew that although a typical patient treated with Solu-Medrol for five days would

relapse in twelve to eighteen months, and that a typical patient treated with H.P. Acthar Gel would relapse in as few as two to three months.

149. Thus, the cost to treat a typical patient with Solu-Medrol would be less than $5,000 over a five year period (approximately four treatment cycles), but the cost to treat the same patient with H.P. Acthar Gel would be almost $700,000 (approximately 30 treatment cycles). As an example, at the Regional Sales Meetings on March 7th- 8th in 2013, held in New Brunswick, New Jersey Blainy Creasy, the region's new Medical Science Liason (MSL) gave a scientific talk about Acthar and its new mechanism of action (MOA) and how they intend to position it in the physician's offices. Stacy Clancy said that *"even though we sell 5 day, the doc's are finding out that it is not working and some patients need another vial."*

150. Plainly, promoting a five-day course of treatment with H.P. Acthar Gel inured to the patient's financial detriment and, more importantly, to the detriment of the patient's health and well-being. Questcor promoted the five-day treatment cycle in order to get both the physician and the patient "hooked" on the substantially more expensive H.P. Acthar Gel in lieu of Solu medrol.

X. Questcor Pays Illegal Kickbacks to Induce Providers to Promote and Prescribe H.P. Acthar Gel for the Five Day Dosing and Pulse Therapy

A. Questcor Disguises its Kickbacks and Off Label Promotion of H.P. Acthar Gel Through its Engagement of Paid Speakers.

151. Questcor knows that under FDA laws and regulations it is not permitted to initiate discussion of off-label uses of H.P. Acthar Gel, or to promote false and misleading comparisons of H.P. Acthar Gel to other drugs. Nevertheless, a key component of Questcor's Fraudulent Marketing Scheme is the use of paid "experts" to influence other doctors to prescribe H.P. Acthar Gel for their patients, including for off-label uses, and to influence patient decision making as well.

152. Thus, Questcor routinely pays preferred doctors and other healthcare providers to make presentations to individual or small groups of doctors in order to encourage them to prescribe H.P. Acthar Gel, or to individual patients. Questcor's Executive Vice President and Chief Business Officer, Steve Cant, explained the program, and confirmed its success in promoting sales, during the company's Q1 2011 earnings call:

> In these [sponsored physician speaker programs], existing Acthar prescribers present to small groups of physicians, their experiences using Acthar and the published efficacy and safety data for Acthar in MS relapses. When combined with follow-up sales calls, these programs appear to be a key driver of our sales growth. Recently, we have been significantly increasing the number of speaker programs being conducted and expect to continue doing so in the future. As [CEO] Don [Bailey] mentioned, we believe that we still have a lot of work to do and a lot of room to grow in the MS market. Our number of Acthar prescribers is growing, but at roughly 500 it's still just a small fraction of the roughly 4,000 neurologists in the US currently being called on by our sales force.

153. In all instances, the speakers are paid to promote only a five-day course of treatment (as opposed to the much longer and even more expensive course of

treatment specified by the FDA) and to make false and misleading superiority claims with respect to Solu-Medrol. As an example, on March 15, 2013 Relator Pratta had a dinner program for physicians in which Dr. Papa-Rugino was the speaker. She openly promoted Acthar off label and when she got to the dosing slide, she said that *"the dose is a five day dose."*

154. Questcor chooses its speakers based on their enthusiasm and track record for prescribing the five day course of treatment. Thus, before a doctor will be considered for Questcor's speaker program, he or she must prescribe H.P. Acthar Gel for at least five patients who then actually take delivery of the drug and undergo a course of treatment with it. Questcor then pays the doctor to give promotional talks to physicians and prospective patients. Sumul Raval, M.D[14] is a Doctor in Lisa Pratta's territory who is now prescribing Achtar. On March 7, 2014, John Stabile directed Lisa Pratta to go see Dr. Raval and *"give him more talks so he will give us more referrals. A referral for each talk."*

155. Questcor recruits physician assistants and nurses to become paid speakers for H.P. Acthar Gel if they have the ability to influence a large volume of prescriptions. Thus, for example, Relator Strunck was encouraged by Regional Manager Ken Miller to recruit Nicole Buonanno to be a paid speaker. Ms. Buonanno is a physician assistant for Dr. Misha Kucherov (Poughkeepsie, NY), and she has

[14] On February 24th Dr. Raval gave a patient program talk. When it came to dosing he stated, *"the dose of Achtar is 5 days. Everyone only uses it for 5 days"*. Dr Raval was speaking from the materials but also ad libbed. The speaking opportunities he has received are tied to referrals. He typically puts in a referral either right before or after he speaks.

primary responsibility for treating Dr. Kucherov's patients who suffer from MS. Mr. Miller told Relator Strunck that if he could confirm Ms. Buonanno as a paid speaker, she would put all of Dr. Kucherov's (approximately 200) MS patients on H.P. Acthar Gel. To her credit, Ms. Buonanno declined Questcor's proposal because she was not persuaded that H.P. Acthar Gel is an equally effective or superior therapy for acute exacerbations of MS.

156. Questcor speaker programs were and may still be are coordinated through a third-party vendor called MedLogix, (and possibly others). Questcor pays for three different types of speaker presentations: (i) Health Care Provider speaker programs; (ii) Meet-the-Expert speaker programs; and (iii) Live Patient speaker programs. Although the presentations are offered under the guise of providing "fair and balanced" information, they are nothing of the sort. Speakers are selected based on the volume of H.P. Acthar Gel prescriptions they write, and the extent to which they will be strong advocates for prescribing H.P. Acthar Gel for a five-day protocol.

157. Paying doctors to give these off-label promotional presentations to peers and patients is a common and broadly-accepted sales practice at Questcor because the primary focus is on growing market share at all costs. Not coincidentally, most doctors who agree to prescribe H.P. Acthar Gel are rewarded with speaker training and dollars. Attached hereto as Exhibit L is an extensive list of "speakers" trained on H.P. Achtar Gel.

158. In 2014 Questcor began removing people from the speaker list based on the frequency of referrals made by the Physician so that they can create "space." As an

example, in Lisa Pratta's Region, her Manager, John Stabile looked at how many referrals the speaker's have written in the year and also how many times the doctor was used for Health Care Provider and Patient programs. Stabile asked Pratta directly if he could make Dr. PapaRugino inactive, because *"she has not put in many referrals this year"* and not been used that much. See the text message from Stabile to Lisa regarding *"cleaning up the database"* (that demonstrates such conversations took place) which is attached hereto as Exhibit M repeated below:.

> Thank u for your help today
> Hey Lis··· Do you think it would be OK
> to deactivate Papa-Rugino from the
> ~ speaker bureau, at least for a while?
> We are at our company cap and can't
> add new speakers until we clean up
> the database. She's only been used
> once in a year for a patient program
> and 0 HCP programs. Let me know,
> thanks! Let me think about it. I am seeing
> her tomorrow and she has come around
> this past quarter.

1. Health Care Provider Speaker Programs

159. Health Care Provider ("HCP") speaker programs typically occur over dinner (sometimes called "Dine-Around" programs) at fancy restaurants (e.g. "42" at the Ritz-Carlton Westchester, NY) or during a catered lunch at a physician's office, and they involve a single paid speaker who proactively promotes the five-day Brod Protocol to the physicians who attend. The threshold for what will qualify as a reimbursable

speaker program is very low: only three people need attend (and they need not be physicians). Even spouses are permitted to attend these events.

160. Questcor imposes no limit on how much its sales force may spend on these meals, and instead encourages the sales force to spend as much as possible on the theory that a lavish meal will induce favorable script writing. During his tenure with Questcor, Relator Strunck spent approximately $5,000 per month on catered lunches, and $2,500 to $4,000 per month for dinners and speaker honoraria, all reimbursed by Questcor with the approval of his regional manager.

2. Meet-the-Expert Speaker Programs

161. Meet-the-Expert speaker programs tend to be one-on-one promotions geared toward specific doctors and practices. These programs typically occur by (i) telephone (such as when the Questcor sales specialist will call the speaker from a sales target's office, and ask the speaker to promote directly to the target), (ii) by video (such as when the Questcor sales specialist will play a promotional presentation in DVD format for the sales target, who necessarily cannot ask any questions of the speaker), or (iii) in one-on-one presentations over a meal. In each case, the speaker is paid to proactively promote the five-day Brod Protocol as being superior to Solu-Medrol. Dr. Brod himself participates as a paid speaker during some of these interactions, both live and via DVD.

162. Drs. Alice Rusk and Walter Camp (Stamford/Greenwich, CT) prescribed a five day course of treatment with H.P. Acthar Gel for at least two patients after

having been entertained with monthly lunches and a "meet-the-expert" DVD presented by Dr. Brod.

3. Live Patient Speaker Programs

163. Live Patient speaker programs are events at which physicians are paid to speak directly to groups of patients, typically at a commercial venue (such as a hotel) with a meal provided. The purpose of these programs is to encourage patients to ask their doctors to treat them with the five-day Brod Protocol, and thus only physicians who prescribe H.P. Acthar Gel according to that protocol themselves are selected for these programs.

164. Questcor has designed a series of promotional materials, including paper materials and DVD presentations, that it encourages sales specialists to distribute at Live Patient programs. These materials include: (i) an "Injection Guide with Injection DVD"; (ii) a "Select Acthar for Select Patients" DVD; (iii) an "HITS Patient Flashcard"; (iv) a "Patient Waiting Room Checklist"; and (v) water bottles and tote bags that include the H.P. Acthar Gel logo.

165. The launch materials for Questcor's Live Patient speaker programs confirm that their purpose is to promote sales and generate a return on investment ("ROI"). Indeed, a training slide deck for a July 25, 2011 training program identifies the following "Strategies for Success":

- Partnering to drive attendance
- Advocacy groups
- Physician offices/MS centers/Hospitals

- Targeting appropriate areas to ensure pull through
- Adequate pool of Acthar writers
- Pool of very patient influenced HCPs [emphasis in original]
- Ensure effective follow up to record ROI
- Good planning is critical for success

B. Questcor Pays Illegal Kickbacks to Physicians in Order to Induce Them to Promote and Prescribe H.P. Acthar Gel.

166. Questcor knows that it may not directly pay doctors for their decision to promote or prescribe H.P. Acthar Gel. Nevertheless, Questcor routinely induces doctors to promote and prescribe H.P. Acthar Gel by providing them with things of value as a quid pro quo for their support. Specifically, Questcor routinely induced doctors to promote and prescribe H.P. Acthar Gel by

(i) bribing doctors' (junkets, gifts, etc) and their staff to prescribe and promote H.P. Acthar Gel;

(ii) funneling research dollars to physicians who agree to promote and prescribe H.P. Acthar Gel;

(iii) providing exorbitant speaker fees to doctors who become vocal advocates for H.P. Acthar Gel;

(iv) paying sham consulting fees to doctors who agree to speak to sales representatives about how best to sell H.P. Acthar Gel; and

(v) providing free prior authorization assistance services to physician practices.

1. Questcor Bribes Physicians And Their Office Staff to Induce Them to Prescribe and Promote H.P. Acthar Gel.

167. Questcor faces a significant challenge in its effort to promote H.P. Acthar Gel for exacerbation of MS (its primary clinical use) because its primary competitor drug, Solu-Medrol, is cheaper, requires a shorter course of treatment and is the standard-of-care for treating exacerbations of MS. Questcor's response to this challenge has been to bribe physicians to prescribe and promote H.P. Acthar Gel instead of Solu-Medrol.

a. Bribes to Office Staff

168. Many of the physicians who treat patients with multiple sclerosis refuse to meet with pharmaceutical sales specialists. Indeed, approximately 75% of the physicians on Relator Strunck's Questcor-provided call list were "no see" physicians, meaning that they had policies that they would not speak with pharmaceutical sales representatives. One way in which Questcor has overcome this threshold obstacle is to bribe office staff to arrange such meetings.

169. Beginning as early as initial sales training, Questcor has encouraged its sale specialists to provide gift cards to physicians' office staff in order to obtain access to the physicians themselves. Relator Strunck specifically received this instruction from his trainer, Roger Lovett, and from VP for Commercial Operations Eldon Mayer. The message was reinforced by his regional manager, Ken Miller, who (falsely) explained that this conduct was permitted by law because Questcor is a device manufacturer, and not a pharmaceutical company.

170. For example, Questcor, through its Regional Managers, encourages its sales specialists to provide gift cards for popular retailers (e.g., Dunkin Donuts, Starbucks) in exchange for setting up meetings with the physicians they serve. These gift cards also have the effect of rewarding the office staff for the time they will be expected to spend managing prior authorization and reimbursement requests for H.P. Acthar Gel.) Questcor routinely reimbursed Relator for these expenses, which he typically described as "gi certificates" and which Questcor coded as "FPE" in its reimbursement system.

171. Among the offices at which Relator Strunck was directed to, and did, use retail gift cards to facilitate the off-label promotion of H.P. Acthar Gel was the office of Drs. Alice Rusk and Walter Camp (Stamford/Greenwich, CT). Their practice treats predominantly Government Program beneficiaries, and Questcor's improper promotions induced Drs. Rusk and Camp to prescribe a five-day course of treatment with H.P. Acthar Gel for at least two patients who were suffering from acute exacerbations of MS.

172. Although Relator Strunck was encouraged by his Regional Manager to, and did, use relatively modest amount gift cards (up to $50) to incentivize physicians' office staff to assist him, other sales specialists were more lavish in the gifts they doled out. For example, when sales specialist Jessica Goguen was not "hitting her numbers" her Regional Manager at Questcor told her to ride with sales specialist Cory Prato (Brooklyn), who was considered to be a shining star within the company. Goguen took the advice, and observed Prato dole out $500 gift certificates

in order to incentivize practitioners and their staff. Goguen was appalled by this practice, complained about it to her Regional Manager, and said she would not replicate it herself. She received such a hostile reception to this statement that she voluntarily resigned her position with Questcor.

173. As a practical matter, there is no limit on the number or dollar amount of gift cards that Questcor will permit its sales specialists to distribute. All requests for reimbursement of such expenses are routinely approved by Regional Managers with full knowledge of what the reimbursement is for, and its intended purpose. On the rare occasion when Relator Strunck's Regional Manager rejected a reimbursement request (perhaps 5% of all requests), the rejection was accompanied by an instruction on how to rephrase the request so that the expenses would be reimbursed dollar-for-dollar.

174. Questcor tells its sales specialists that they are permitted to provide gift cards in exchange for access and approval because Questcor is a manufacturer of medical devices, not a pharmaceutical company.

b. Bribes to Physicians

175. Questcor recognizes that, because of Solu-Medrol's therapeutic and financial advantages, getting in front of prescribing physicians is only half the promotional battle. Persuading them to switch from Solu-Medrol to H.P. Acthar Gel is not easy. Thus, the company encourages its sales specialists to incentivize physicians to make that switch by providing them with things of value.

176. Questcor holds out Jessica Sukkanen, a sales specialist whose territory includes Nevada and Southern California, as a shining example of what the company considers to be the ideal sales specialist. Indeed, when Relator Strunck was hired by Questcor, his Regional Manager told him that he should call Ms. Sukkanen for advice.

177. Relator Strunck called Ms. Sukkanen, who told him that she has had great success promoting a five-day course of treatment with H.P. Acthar Gel to the physicians in her territory. When Relator Strunck asked her how she was able to persuade physicians to make the switch from Solu-Medrol, she told him that she incentivize them by taking them on paid junkets in Las Vegas, entertaining them with lavish meals, and rewarding them with gift cards and spa treatments - all fully reimbursed by Questcor. She even bragged that she had particular success with physicians of Asian descent by "doing karaoke" with them, again, with Questcor's full knowledge and approval.

c. Meals and Social Happy Hours

178. Another way in which Questcor bribes physicians to switch from Solu-Medrol to H.P. Acthar Gel is by sponsoring meals and "happy hour" social gatherings for physicians and their staff. Although Questcor nominally requires that each such event include at least five "guests" in order to be reimbursed, in Relator Strunck's experience, the company imposes no limit on how much a sales specialist can spend in this fashion if doing so will "drive business."

179. For example, Relator Strunck was encouraged to, and did, incentivize Dr. Nilay Shah, who practices in Mt. Kisko, NY and Jersey City, NJ, to switch from Solu-Medrol to a five day course of treatment with H.P. Acthar Gel in part by sponsoring a series of catered lunches for his office every other week. This, combined with other efforts described below, succeeded in persuading Dr. Shah to prescribe a five-day course of treatment with H.P. Acthar Gel for eight of his MS patients (although three refused to take delivery of the drug). As discussed infra, Relator Strunck also incentivized Dr. Shah by telling him that upon prescribing the drug for five patients, he could become a paid promotional speaker for N.P. Acthar Gel, which he did. Dr. Shah practice treats a significant number of Government Program (Medicare Part D) patients.

180. Relator Strunck was encouraged to, and did, induce Drs Andrew Decker and Cordelia Schwarz (White Plains, NY) and Sarla Devi (Yonkers, NY) to prescribe a five-day course of treatment with H.P. Acthar Gel in lieu of Solu-Medrol. Questcor and Relator Strunck did this by treating the doctors, and Dr. Devi's husband, to a lavish dinner at the restaurant "42" (located in the Ritz-Carlton Westchester hotel) during which Dr. Mary Ann Picone (Teaneck, NJ) was paid to actively promote the five-day course of treatment with H.P. Acthar Gel. Following the dinner, Dr. Devi said that she would implement the five-day Brad Protocol for her patients, and she did. Drs, Schwarz and Decker declined. Relator Strunck believes that approximately 80% of Dr. Devi's patients are Medicare beneficiaries.

181. Drs. Schwarz and Decker practice with the West Med Medical Group. At his regional manager's direction, Relator Strunck sponsor several "happy hour" social events for their office in an attempt to persuade them to switch from Solu-Medrol to H.P. Acthar Gel. To their credit, Drs. Schwarz and Decker refused to make the switch because they were not comfortable with the lack of supporting data.

2. Questcor Illegally Uses Research Money to Encourage Doctors to Prescribe and Promote H.P. Acthar Gel.

182. Questcor routinely sponsors independent investigations conducted by physicians as a means by which to (i) provide a kickback to doctors who prescribe H.P. Acthar Gel, and (ii) market H.P. Acthar Gel for off-label use.

183. An example of this strategy is the situation of Dr. Brod *(author of the aforementioned of the Brod Protocol)* of the University of Texas. Questcor has paid Dr. Brod to conduct several investigational trials of H.P. Acthar Gel, including one to determine the efficacy of a five-day course of treatment. Questcor pays Dr. Brod $500 per patient for the trials, and subsequently has paid him handsomely to promote the results of his trials to physicians across the country. These trials are of dubious scientific value because they were neither placebo-controlled nor double-blind. None have been published in peer-reviewed journals, none have led to an application to expand the FDA approval for H.P. Acthar Gel, and none have demonstrated that H.P. Acthar Gel is any more efficacious than Solu-Medrol. These facts, notwithstanding, they studies, transformed Dr. Brod into a high volume

prescriber and a very highly compensated speaker for Questcor. In addition to all of the above, Brod is scheduled routinely for visits with Doctors and even accompanies sales representatives often on calls to Doctors, so much so, that he is hard schedule.

184. When Relator Strunck joined Questcor, his Regional Manager, Ken Miller, instructed him to jointly approach Dr. Mustafa Kahn (of Kingston Neurological Associates in Kingston, NY) with MSL Sagar Shah and offer to pay Dr. Kahn to conduct an "investigational trial" on H.P. Acthar Gel, in which Dr. Kahn would be paid per enrolled patient. Miller explained that this was a way to encourage Dr. Kahn to begin prescribing H.P. Acthar Gel, and that Dr. Kahn was considered to have the potential to be a high volume prescriber. Relator Strunck followed Miller's instructions, but was unable to arrange the meeting until June 8, 2011.

185. Another way in which Questcor sought to induce the physicians at Kingston Neurological Associates to prescribe the five-day Brod Protocol of H.P. Acthar Gel was by providing a $500 "grant" that Kingston requested in July 2011 to support a joint program between Kingston and Benedictine Hospital.

186. Dr, Sean Orr of Jacksonville, Florida is another high-volume prescriber that Questcor has rewarded with highly profitable investigational trials of dubious scientific value. These trials transformed the sales specialist assigned to Dr. Orr, Jason Ambrose, into one of Questcor's most successful - and highly compensated - sales specialists.

187. Dr. Regina Berkovich of the University of Southern California is another high volume prescriber that Questcor has rewarded with highly profitable investigational trials of dubious scientific value. These trials helped to transform the sales specialist assigned to Dr. Berkovich, Jessica Sukkanen, into one of Questcor's most successful -- and highly compensated - sales specialists. As an example of the foregoing, Dr. Regina Berkovich presented a Questcor supported study at the 65th National AAN meeting held on March 10, 2013 in San Diego for use of Acthar in pulse therapy. [See Exhibit J attached hereto] Questcor Sales representatives and Key Opinion Leader sales liasons Joe Citkowski and Regional Manager John Stabile use this as a sales tools when soliciting Doctors, stating that Dr. Berkovich uses it for three days a month.

188. Dr. Andrew Wu of San Francisco, California is another high-volume prescriber that Questcor has rewarded with highly profitable investigational trials of dubious scientific value.

189. As indicated above, Questcor induced Dr. Nilay Shah (Mt. Kisko, NY/Jersey City, NJ), to prescribe a five-day course of treatment with H.P. Acthar Gel for eight of his MS patients (although three refused to take delivery of the drug) by telling him that upon prescribing the drug for at least five patients, he could become a paid promotional speaker for H.P. Acthar Gel, which he did. Dr. Shah was given three speaking programs in a single day in July 2011, and he was paid $2,000 per program. These three presentations combined for a total of thirty minutes, plus additional time spent traveling among the offices. Thus, Dr, Shah was paid $6,000

for fewer than three hours of work. The real purpose of these payments were an inducement, which is clear when the payment is compared to the actual time spent.

3. Questcor Illegally Uses Speaker Fees and Lavish Meals as a Means to Compensate Healthcare Providers Who Prescribe H.P. Acthar Gel.

190. Questcor knows that many healthcare providers are eager to supplement their income through drug-maker speaker programs. Thus, Questcor's speaker program is designed and intended both to induce off-label use of H.P. Acthar Gel, and to provide a financial inducement for the healthcare providers who do so.

191. Questcor trains its sales specialists to identify potential speakers based on the volume of MS patients they treat. Physicians (and physician assistants and nurses) are ranked in one of ten deciles based on volume potential. In order to be selected as a qualified speaker, Questcor requires that the healthcare provider first write at least five prescriptions for H.P. Acthar Gel, thereby demonstrating his/her commitment to the drug (and providing a healthy profit for Questcor).

192. Those who are selected for the paid speaker program are required to participate in paid speaker training that occurs by telephone. Thereafter, approved speakers can receive a fee of $2,000 per presentation, or $6,000 per day (assuming a maximum of three presentations per day). Questcor does not impose a cap on speaker fees, and some speakers, such as Dr. Brod and Dr. Berkovich are considered "national" speakers who can earn even more per presentation, The more vocal advocates can earn a substantial amount giving promotional talks for Questcor.

Relator Strunck estimates that Dr. Brod delivers about 100 paid presentations a year, and is paid accordingly.

193. Although Questcor pays its speakers at the very high end of the industry standard, its standard for what will qualify as a "speaker program" that is eligible for such payment is very low. As long as there are a mere three people in attendance - and they need not be physicians - the speaker is eligible for a full fee. Even spouses are permitted to attend.

194. That speaker fees really are a thinly-veiled effort to reward healthcare providers who prescribe H.P. Acthar Gel is confirmed by Relators experience that approximately 90% of all prescriptions for H.P. Acthar Gel are written by Questcor-approved speakers. Moreover, given that H.P. Acthar Gel has been FDA approved for more than fifty years, and given that virtually all of Questcor's promotion is focused on exacerbation of MS - an indication for which H.P. Acthar Gel was approved more than forty years ago - the need for any speaker programs on the subject is dubious at best. This tends to confirm that speaker fees are merely a quid pro quo for the decision to prescribe for the five day dosing regimen. Exhibit L is a list of 88 persons who are trained and approved by Questcor to speak on the use of H.P. Acthar Gel for the treatment of MS, and an additional 30 persons who are newly nominated and pending contracts and training.

195. While Questcor's threshold for who may qualify for the speaker program is quite low, and based solely on the healthcare provider's willingness to prescribe H.P. Acthar Gel, many healthcare providers decline the lucrative

incentive because they are skeptical of the drug's efficacy, safety and cost. Thus, for example, several physicians who Relator Strunck courted for the speaker program - including Ute Traugott (Rye, NY), Renee Elkin (Bronx, NY) and David Duncan (Mt. Kisco, NY) - refused the inducement.

4. Questcor Illegally Uses Sham "Consulting Fees" to compensate Doctors Who Prescribe and Promote H.P. Acthar Gel.

196. Another way in which Questcor has illegally incentivized and rewarded physicians to prescribe and promote H.P. Acthar Gel is through the payment of sham consulting fees. For example, Questcor has paid Dr. Pere $2,000 per program to talk to Questcor's own sales specialists about how to sell H.P. Acthar Gel to physicians.

5. Questcor Induces Physicians to Prescribe H.P. Acthar Gel by Offering Free Business Services, Which Also Have the Effect of Generating Fraudulent Reimbursements.

a. The Acthar Support and Access Program (ASAP)

197. Questcor knows that virtually all prescriptions for H.P. Acthar Gel will require prior authorization if they are to be reimbursed by Government Programs or private insurance. Questcor also knows that because of the drug's high cost, limited approval and ominous safety profile, Government Programs and private insurers typically set rigid requirements for when they will approve reimbursement for H.P. Acthar Gel.

198. Questcor also knows that the process for obtaining prior authorization for H.P. Acthar Gel - even for a patient who legitimately requires the drug for use within its FDA approval - can extract a significant time and financial burden on a. busy medical practice.

199. Thus, Questcor established the Acthar Support and Access Program (ASAP), which operates like a reimbursement "hub" for physicians. The program is managed by Curascript (the specialty pharmacy that is the exclusive distributor for H.P. Acthar Gel), and it handles all aspects of the prior authorization process for physicians who prescribe H.P. Acthar Gel. Questcor probatively promotes the ASAP program to physicians because it knows the program will add value to a physician's business, and induce the physician to prescribe H.P. Acthar Gel in lieu of Solu-Medrol.

200. The first step in the ASAP program occurs when Questcor's sales specialist visits with a medical practice. At the direction of Questcor regional managers, the sales specialists, including Relator Strunck, probatively tell physicians that the only way that they are allowed to prescribe H.P. Acthar Gel is by enrolling the patient in the ASAP program, even though that simply is not true.

201. Sales specialists are trained to, and do, tell physicians that they personally will benefit from the ASAP program because Curascript will undertake responsibility for managing the prior authorization process from beginning to end - a substantial benefit to physicians and their staff. They also tell physicians that enrolling the patient in the ASAP program makes the patient eligible to participate

in (i) Questcor's Co-Pay Assistance Program; (ii) Questcor's Patient Assistance Program; and (iii) the National Organization of Rare Disorders (which is not affiliated with Questcor).

202. Questcor sales specialists are trained to, and do, tell physicians that the first step in the ASAP program is for the physicians to complete an ASAP enrollment form for each patient, listing among other things the patient's biographical data, insurance data, diagnosis and specific prescription (i.e. number of vials and syringes).

203. Questcor instructs its sales specialists to tell physicians that, in order to overcome prior authorization obstacles, both the ASAP enrollment form and the patient's chart must indicate that the patient previously, but unsatisfactorily, tried intravenous Solu-Medrol or oral prednisone even if that is not true. Relator Strunck did this at the direction of Regional Manager Ken Miller, and he understands that other sales specialists, including Stacy Clancy and others in her Philadelphia-area sales district, did this as well.

204. In Relator Strunck's experience, physicians and their staff who agreed to prescribe H.P. Acthar Gel did not "balk" at the instruction to falsely state on the ASAP enrollment form and in patient charts that the patient had tried Solu-Medrol or oral prednisone and had an unsatisfactory result, Instead, ironically, the most frequent "push-back" that Relator Strunck received from the physicians he called on was that their patients were responding well to treatment with Solu-Medrol, and that they did not require a different therapy.

205. Among the physicians who either directly or through their staff agreed to (i) prescribe an off label five-day course of treatment with H.P. Acthar Gel for acute exacerbations of MS, and (ii) falsely state for reimbursement purposes that the patient had tried but failed with alternate therapy, were Dr. Alice Rusk (Stamford/Greenwich, CT), Dr. Nilay Shah (Mt. Kisco, NY) and Dr. Sarla Devi (Yonkers, NY).

206. Once Curascript receives an ASAP enrollment form, it notifies Questcor of the prescription, and a Questcor Regional Reimbursement Manager (for Relator Strunck, it was Michael Hoffman) relays the information to the sales specialist assigned to the prescribing physician. The sales specialist then is required by Questcor to contact the prescribing physician to provide instruction as to how to facilitate payment, perhaps through the Co-Pay Assistance Program or the Patient Assistance Program, discussed infra, when Curascript calls to complete the transaction.

207. On the rare occasion that a prior authorization request is denied by a Government Program or private insurer, Questcor instructs its sales specialists to "coach" physicians and their staff on how to "win" the appeal by, among other things, overwhelming the insurer with so many reimbursement requests and appeals that it ultimately relents. This cynical strategy has proven to be quite successful.

208. Questcor's Associate Director for Specialty Distribution and Payer Relations, Jason Camp, authored an email to the entire sales force and senior

Questcor sales management on June 20, 2011 in which he stated that as a result of the Questcor's strategy of "*continually pressuring Federal BCBS by requiring them to review each Acthar referral at their weekly Physician Review meetings*" and *"continually tying up their resources,"* Federal BCBS had *"ultimately conceded and has agreed to provide authorization for all Acthar MS referrals that meet [specified] coverage criteria"* (i.e. active flare, detailed history with Solu-Medrol and current disease modifying therapy). Mr. Camp's email confirmed that Questcor's strategy had been to:

1) Work with HCPs to submit referrals that clearly met coverage criteria (in active flare), and have detailed history of patient;

2) Coach HCP offices to appeal, and work with them throughout the process[; and]

3) ROSS team identifying key decision-makers at Federal BCBS responsible for the authorization process and called on them continually to make them justify each denial.

209. Mr. Camp described this development as *"an important breakthrough with Federal BCBS, one of the most difficult payers in the country."* According to Mr. Camp, although Federal BCBS had approved only 2 of 40 prior authorization requests in 2010, it approved 14 of 15 requests between April 18, 2011 and June 20, 2011 alone.

210. Questcor's ASAP program is improper not simply because it provides a valuable service to physicians to induce them to prescribe H.P. Acthar Gel in lieu of less expensive, equally or more effective alternatives, but also because the program itself is deceptive in the manner in which it encourages reimbursement by Government Programs.

b. The Co-Pay Assistance Program and the Patient Assistance Program

211. Questcor's Co-Pay Assistance Program is a program by which Questcor provides insurance co-pay assistance to a patient whose household income does not exceed a certain threshold, which Relator Strunck believes to be in the range of $50,000 per year. For these patients who are suffering from MS, including patients who are Medicare beneficiaries, Questcor attempts to keep their co-pay to $50 or less.

212. Questcor's Patient Assistance Program is a program by which Questcor provides full reimbursement for uninsured patients whose household income does not exceed a certain threshold. Questcor instructs its sales specialists to actively promote the Co-Pay Assistance Program and the Patient Assistance Program to healthcare providers, using it as a means to overcome their objections to prescribing H.P. Acthar Gel in lieu of Solu-Medrol. Questcor places particular emphasis on promoting these programs for patients who are Medicare beneficiaries, telling physicians that they should ignore the high cost of the drug since the patient's out-of-pocket cost will be, at most, $50.

213. Questcor historically "self funded" the patient assistance programs. Questcor used the PAP as a sales tools and illegal inducement. The Sales Representative who specifically this the PAP as such are Mike Hoffman, Jason Camp, Art Veno, Rob Santa, Cris Hoven, Corrie Prato, Bob Bobeck, Nick Brunetti, Nevan Rushing.

214. The U.S. Department of Health and Human Services, Office of Inspector General, has recognized that programs such as Questcor's Co-Pay Assistance Program and Patient Assistance Program present significant potential for fraud and abuse, particularly if the practice is intended to induce or reward referrals of Federal health care program business. *See OIG Advisory Opinion 09-04 (May 11, 2009) (addressing a tax-exempt, charitable organization's practice of providing financial assistance with cost-sharing obligations associated with certain advanced diagnostic testing owed by financially needy patients, including Medicare beneficiaries); OIG Advisory Opinion 06-10 (September 14, 2006) (addressing a tax-exempt, charitable organization's practice of providing certain therapy management services and assistance with Medicare cost-sharing obligations to financially needy Medicare beneficiaries).*

c. Reimbursement Advisory Boards

215. Additionally, Questcor has sponsored "Reimbursement Advisory Boards" in which a Questcor representative, such as Jason Camp, hosts a dinner program for physician office staff (identified by sales representatives based on their script writing potential) during which he instructs them on how to navigate the

prior authorization process and pays them $500 - $1,000 for their time. Examples of Reimbursement Advisory Board events include:

(i) an event for five people at "Shadows on the Hudson" restaurant (Poughkeepsie, NY) on March 1, 2011 led by Questcor's Regional Reimbursement Manager Michael Hoffman and paid speaker Dr. Alan Perel;

(ii) an event for seven people in Patterson, New Jersey on July 21, 2011 led by Questcor's Product Director for MS Marketing (Sangeeta Prasad) and Questcor's Associate Product Manager for MS Marketing (Andrea Gasparino); and

(iii) an event in Northern New Jersey on August 2, 2011 led by Questcor sales specialist Christine Trafficant).

(iv) Questocor and Mallinckrodt have continued this practice but it grew in size and scope. They would fly the doctors to various locations. The marketing department began heading these meetings. Many of the doctors were flown to Las Vegas or Orlando for a weekend meeting. Mallinckrodt then started calling them "speaker training" meetings. As an example Amos Katz M.D. after he attended one of these meetings in 2016 in Orlando. The marketing department would have the physicians review potential marketing materials and have them give feedback.

C . Questcor Uses Free Vials of Acthar As An Inducement to Physicians In Order to Induce Them to Promote and Prescribe H.P. Acthar Gel.

216. Questcor maintains a "free vial" Program which was limited to use for children in hospital with infantile spasms.

217. Questcor then illegally employed this program to induce referrals for H. P. Achtar Gel. As used improperly with MS, the program should more aptly be referred to as *"Prescribe One and Get One Free"* Program.

218. In order to induce referrals, physicians are offered a free vial *(currently valued at over $38,000 dollars per vial)* for a patient, and when "approved"for the program, it is expected and required that the physician will also simultaneously put in a referral for a paid vial for that patient, essentially, creating a one for one trade off.

219. The essence of the "free vial" program *(currently valued at over $38,000 dollars per vial)* is to induce neurologists with one free vial for each patient to get them started on a five day dosing regimen or a pulse therapy program. While it is unlimited for the physician, it is limited to one vial per patient with the idea that physician orders the vial for that patient at the same time.

220. Joe Citkowski, (the sales representative and Key Opinion Leader (KOL) for Lisa Pratta's region) contacted her by phone on or about October 2, 2013. Referring to Dr. Amos Katz, Citkoswki told Lisa ". . . *I am signing these offices up*

for our free sample vial program[15]. Citkowski's goal was to present the "free vial" program to Dr. Katz, telling him that *"he could use a free vial for each patient to get them started and then to submit a referral for a 5 day course of therapy to Medicare or the patient's commercial insurance."*

221. The proposal to Dr. Katz which was made by Joe Citkowski (KOL) and John Stabile (Regional Manager) was reviewed and approved by Darlene Romine (VP Sales), Jason Camp (Director of Reimbursement), and Eldon Mayer (President). This approval was accomplished via a series of text messages that occurred between December 21st and 22nd, 2014. Attached as Exhibit N are the following:

- Email dated 1/03/2014 from John Stabile, regional Manager to Joe Citkowski (KOL) and Lisa Pratta enclosing the approvals for 5 separate "starter vials" for Dr Amos Katz in connection with the Free Vial program;
- Five (5) separate Sample Request Forms with unique ID numbers for (1) 5 ml vial of H.P. Achtar Gel at the bottom

222. John Stabile, in his email, tasks Citkowski with taking *"the lead with the service and management of the vials in Katz's office"* since he has *"experience from other centers."* Citkowski is also directed to advise Darlene Romaine (VP Sales) when each vial is distributed. It is important to emphasize that this Program, and the five (5) vial authorization, is nevertheless distributed to the Physicians, in this case Dr Katz, on a one for one referral basis, *i.e., get one free and*

[15] This Program is only for hospitals who have patients with infantile spasms

then prescribe one, . . . get one free and then prescribe another and so on. As an example of this, during a training session on January 8, 2014 at Dr. Katz's office to implement the Free Vial Program, Joe Citkowski emphasized to Dr. Katz's nurse, Michelle Emmons, that upon delivery of the free vial (currently valued at over $38,000 dollars per vial), a referral for a paid vial must be received prior to the delivery of a second free vial.

223. A physician, like Dr. Katz can order an unlimited amount of vials. Dr. Katz and other physicians get 1 or 2 forms each time to be used for new and existing patients. Once a physician is "approved" for the program, it is a blanket approval.

224. Citkowski stated that he is doing this now for Dr. Dina Jacobs MD at the University of Pennsylvania Hospital who has begun to subscribe based on the foregoing. He also advised Lisa that he was completing pre filled out referral forms for Dr. Jacobs. Citkowski stated that he *"sold Acthar to Dr. Jacob using the 5 day (one vial) dosing and he is filling our her forms for the 5 day dosing."*

225. John Stabile advised Relator Pratta that one physician has used 100 free vials, but did not name the physician. This program is meant to induce new users to try Achtar and induce existing referring physicians to use more.

D. Questcor Violated Multiple State' Bans on Gifts For Physicians

226. Doctors who have close relationships with drug makers tend to prescribe more, newer and pricier drugs regardless of the drugs' value compared to

less expensive medications. *See Gardiner Harris, Doctors' Ties to Drug Makers are Put on Close View, N.Y. TIMES, March 21, 2007, available at http:llwww.nytimes.com12007/03/21 /us/2 I drug.html?] =2&pagewanted=l &ref--us&ores login.* To contain the costs associated with such "close relationships" among drug makers and healthcare professionals, several states enacted regulations beyond those provided by federal law and relevant state and federal anti-kickback laws discussed in greater detail infra. Three of these states - Massachusetts, Minnesota and Vermont - curtailed much of the "wining and dining" that drug makers had used to influence healthcare professionals and prohibited a variety of payments and gifts as having no purpose other than to establish a "close relationship." These three states and several others, including California, Maine, West Virginia and the District of Columbia, established reporting requirements related to marketing to healthcare professionals

227. Through its regular sales practices described herein, Questcor engaged in direct violations of the gift laws of Minnesota and likely other states by, inter alia, paying for dinners for providing business consulting services and other gifts that had no bona fide medical explanation or reason.

228. These practices are part and parcel of Questcor's sales practices nationally, and the violation of such gift laws is known to, and countenanced and supported by, Questcor regional and national sales managers.

XI. Defendant's Fraudulent Statements and Actions Were Material to the Government's Payment Decision and Violate The False Claims Act

A. Materiality Under The FCA

229. Section 3729(b)(4) of the FCA defines materiality similar to that found in other federal statutes: "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

230. The Supreme Court, in *Escobar*,[16] addressed whether or not whether Section 3729(a)(1)(A)'s materiality requirement is governed by Section 3729(b)(4) or derived from the common law, stated that under any understanding of the concept, materiality "look[s] to the effect on the likely or actual behavior on the recipient of the alleged misrepresentation."

231. Using Tort and Contract law as examples, the *Escobar* Court stated a "matter is material" in two circumstances: (1) "[It] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant new or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not. Restatement (Second) of Torts § 538, at 80. Materiality in contract law is substantially similar. See Restatement (Second) of Contracts§ 162(2), and

[16] *United States ex rel. Escobar* 579 U.S._, 2016 WL 3317565, slip op., No. 15-7 (June 16, 2016),

Comment C, pp. 439, 441 (1979). ("A misrepresentation is material only if it would 'likely ... induce a reasonable person to manifest his ascent,' of the defendant, knows that for some special reason (the representation) is likely *to* induce the particular recipient *to* manifest his ascent to the transaction.) [emphasis added)

B. Defendants Violations of The Anti Kickback Act ("AKS") Are Material and Constitute a False Express Certification Under the FCA

232. The Fraudulent Marketing Scheme, including the kickbacks described herein, violates the Federal Anti-Kickback Act[17] ("AKS") and was implemented with the intent to induce physicians to agree to prescribe H.P. Acthar Gel, knowing that such prescriptions would be reimbursed by Government Health Care Programs, through a pattern of corrupt and illegal conduct, in violation of the federal False Claims Act, 31 U.S.C. § 3729.

233. The agreements between physicians and Questcor were a clear quid pro quo. Questcor offered participation in these quid pro quo arrangements. Physicians who primarily used Solu-Medrol in lieu of H.P. Acthar Gel were not offered the same valuable benefits.

234. Questcor's Fraudulent Marketing Scheme served its intended purpose, as it induced (i) doctors to prescribe H.P. Acthar Gel in lieu of cheaper alternatives for both on- and off-label uses, and (ii) the submission of claims for

[17] The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b)

those prescriptions for reimbursement by Government Health Care Programs, which did, in fact, provide reimbursements for those off-label uses, were for medically unnecessary uses.

235. At least in part, as a result of Questcor's illegal sales and marketing practices, H.P. Acthar Gel has been heavily used for the treatment of Government Health Care Program beneficiaries.

236. The Federal Courts have determined that compliance with the AKS is material to the Government payment decision and is a precondition of payment. This conclusion is "rendered inescapable when the purpose of the Anti–Kickback Statute is considered within the context of the Medicare statute." *42 U.S.C. § 1395y(a)(1)(A)*. Moreover, courts, without exception, agree that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti–Kickback Statute[18].

237. The Medicare program requires providers to affirmatively certify that they have complied with the AKS. Failure to comply with the kickback

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[18] *See, e.g., Willis v United Health Group,* 2011 WL 2573380 (2011), ("Compliance with the [Anti–Kickback Statute] is clearly a condition of payment under Parts C and D of Medicare); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir.2009) ("Falsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act]."); *Pogue,* 565 F.Supp.2d at 159 ("Legion other cases have held violations of [the Anti–Kickback Statute] ... can be pursued under the [False Claims Act], since they would influence the Government's decision of whether to reimburse Medicare claims."); *Rogan,* 517 F.3d at 452 (rejecting the argument that a kickback was immaterial to the validity of Medicare and Medicaid claims); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir.2004) ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.");

laws, therefore, is, in and of itself, a false statement to the government."); *United States ex rel. Smith v. Yale Univ.*, 415 F.Supp.2d 58, 91 (D.Conn.2006). A false certification establishes the "falsity" of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA stating "each and every claim submitted under a contract, loan guarantee or other agreement which was originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim." S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274. Medicare Regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement and as a condition to governmental payment, providers must certify that they are in compliance with the terms on the Provider Agreement; *Bidani,* 264 F.Supp.2d at 615–16 (finding a violation of the Anti–Kickback Statute "material to the government's treatment of claims for reimbursement" and that to find otherwise, "would put the government in the position of funding illegal kickbacks after the fact"); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.,* 115 F.Supp.2d 35, 43 (D.Mass.2000) (O'Toole, J.) (holding that alleged violations of the Anti–Kickback Statute were sufficient to state a claim under the False Claims Act, despite no express certification of compliance with applicable law); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 20 F.Supp.2d 1017, 1047 (S.D.Tex.1998) ("[E]xplicit certifications of compliance with relevant

healthcare laws and regulations ... provided evidence that the government conditioned its approval, payment and Defendants' retention of payment funds on those certifications.").

C. Defendants Promoted and Marketed H.P. Achtar Gel For Use That Was Medically Unnecessary in Violation of 42 U.S.C. 1395(y)(A)1)(a)

238. No payments may be made under the Medicare and Medicaid programs for expenses incurred for items and services, including drugs that are not 'reasonably necessary' for the diagnosis and treatment of an illness or injury. See, 42 U.S.C. § 1395y(a)(1)(A).

239. The (i) 'misbranding," (ii) deceptive, false and misleading promotion of H.P. Achtar Gel for off-label uses, (iii) the myriad of kickbacks and illegal incentives described herein, (iv) promoting H.P. Achtar Gel in a manner that is detrimental to the patient's health and well-being and (v) failure to disclose all the promotional and marketing materials to the FDA as required resulted in H.P. Achtar Gel being used in a manner that was medically unnecessary in violation of 42 U.S.C. 1395(y)(A)1)(a). Each of these items, individually and collectively, are material to the Government payers because it is reasonable to infer that this information would be important to the Government in deciding whether to still pay for the drugs.

240. If Defendant had notified the Government Health Care Programs, FDA, States and/or the federal government of the above, they would have refused

to pay for the drug. Using the "reasonable person" standard discussed in *Escobar,* it is certainly plausible to conclude that the Government payers did "attach importance" and it does "influence" payment decisions by the Government to the above facts and circumstances

D. Defendants Failed to Disclose It's Non Compliance With Statutory and Regulatory Requirements in Promoting and Marketing H.P. Achtar Gel

241. An FCA violation occurs under implied false certification when a Defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the noncompliance with a statutory, regulatory, or a contractual requirement. Defendants actions in knowingly distributing H.P. Achtar Gel in an unsafe manner, using deceptive, misleading and false promotion and marketing means and methods, using kickbacks to induce prescriptions, making implicit representations that consisted of half truths regarding H.P. Achtar Gel to Government Agencies such as FDA and the Government Health Care programs, and express representations regarding compliance withe AKS to Federal Payers caused the filing of false claims to the Government by the Pharmacy distributors used by Defendants.

242. These actions make the claim for reimbursement "false" under the FCA because they are legally false as a result of Defendants breach of implied and express certifications which included misleading omissions, that would have been important to the Government Health Care Programs in deciding whether to pay for

the goods. A false certification establishes the "falsity" of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA stating "each and every claim submitted under a contract, loan guarantee or other agreement which was originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim." S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274.

243. Medicare, Medicaid and other government funded health insurance payors, such as TRICARE and the Federal Employee Health Benefits Program do not cover and pay for off-label uses of prescription drugs, except for in very limited circumstances not applicable here. The off-label uses that were the object of Defendants fraudulent marketing scheme were not 'reasonable and necessary.'

244. As a direct result of Defendant's illegal, false, deceptive and misleading off-label marketing and kickbacks of H.P. Achtar Gel, physicians prescribed Achtar for off-label uses and/or for uses which were not reasonably necessary for treatment. Claims for reimbursement for off-label uses, which were not reasonably necessary, and in fact, medically unnecessary uses of Achtar were submitted to the federal government and the States in connection with such prescriptions, giving rise to liability under their respective False Claims Acts. The United States and the States would not have paid these claims for H.P. Achtar Gel but for Defendant's illegal and fraudulent conduct. Such claims were and in violation of 42 U.S.C. § 1395y(a)(1)(A).

245. The FCA expressly imposes liability on individuals who knowingly cause someone else to submit a false claim for payment. 31 U.S.C. § 3729(a)(1). In interpreting the statute, courts have imposed FCA liability on defendants who caused others to submit false claims for payment, even if the party submitting the claim was unaware of its falsity. *See, e.g., United States v. Bornstein*, 423 U.S. 303 (1976).

246. A claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation, such as the AKS, which is material to the government's decision whether to make payment for the goods or services. Within the theory of false certification, there are two further categories: express and implied false certification.

247. A defendant violates the FCA under express false certification when, in conjunction with a request for Federal funds, it certifies that it is in compliance with regulations that are requirements for payment.

248. An FCA violation occurs under implied false certification when a Defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the noncompliance with a statutory, regulatory, or a contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading. *United States ex rel. Escobar* 579 U.S._, 2016 WL 3317565, slip op., No. 15-7 (June 16, 2016),

249. Liability under the FCA occurs under the implied certification for those who submit claims that make fraudulent misrepresentations, which include misleading omissions if they render the representations misleading with respect to the goods or services. Specifically, representations, like the ones present here, that fall within the rule that "half-truths" - representations that state the truth only so far as it goes, while omitting critical qualifying information - can be actionable. *Id.*

250. Defendants are and were aware that it's fraudulent conduct would cause its pharmacies to submit false claims for reimbursement. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d. Cir. 2004) (knowingly assisting in causing the government to pay claims grounded in fraud actionable under FCA); *See also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S.662 (2008) (noting that a defendant is responsible for the "natural, ordinary and reasonable consequences of his conduct").

251 Defendants introduced H.P. Achtar Gel, using deceptive, misleading and false means to market for off-label uses through the use of illegal kickbacks which were medically unnecessary because the safety and efficacy was unsubstantiated for such off label uses.

252. Contrary to FDA regulations[19], Defendant failed to submit specimens of all off label promotional items and advertisements used and described herein at the time of initial publication on a completed transmittal Form FDA–2253. Submission of this document constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Defendants failure to disclose its non compliance constitutes "half-truth" misrepresentations to FDA.

253. In addition to the above, Defendant was and is required, in view of H.P. Acthar Gel's unusual safety profile submit RAMS Assessments[20] to the FDA at periodic intervals. Defendants failed to disclose the manner and methods, including unscientific comparable studies to FDA along with the required reporting. Submission of these reports constitutes a specific and material representation that all relevant and required information is being disclosed and provided to the FDA.

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[19] *See 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81.* Drug labels - including all marketing and promotional materials relating to the drug - may not describe intended uses for the drug that have not been approved by the FDA. *21 U.S.C. §§ 331, 352.* Illegal "misbranding" can result in criminal penalties. *21 U.S.C. § 333.* Defendant must submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA–2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or *"advertisement"* for the product subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and in line with any written communications being submitted to FDA.

[20] See ¶101 . . . *In view of H.P. Acthar Gel's unusual safety profile, the FDA took the additional, non-standard step when it approved H.P. Acthar Gel for the treatment of IS of also approving a Risk Evaluation and Mitigation Strategy (RAMS) that requires Questcor to distribute an approved Medication Guide with each prescription, and also to submit RAMS Assessments to the FDA at periodic intervals following approval of the RAMS. The approved Medication Guide elaborates on the serious and significant side effects associated with H.P, Acthar Gel.*

Defendants failure to disclose its non compliance constitutes "half-truth" misrepresentations to FDA. Failure to comply with FDA REMS requirements can render the company's drug misbranded and result in substantial penalties (e.g., $250,000 to $1 MM cap per violation; $1 MM to $10 MM cap per proceeding).

254. Defendant's Fraudulent Marketing Scheme described herein, included (i) the deceptive, misleading and false claims about Achtar to promote the five dose for acute exacerbations and pulse therapy, and (ii) the myriad types of kickbacks and illegal incentives.

255. These actions inured to the patient's financial detriment and, more importantly, to the detriment of the patient's health and well-being is widespread and has become the "norm" throughout Questcor.

XII. Defendant's Actions Caused the Submission of False Claims

256. Given the rampant and widespread illegal marketing that became commonplace at Questcor, "average" sales cannot be considered to be results of marketing within the confines of the "label." As an example, Relator Lisa Pratta, had 38 total referrals in 2013. Except for times when Joe Citkowski (her KOL) and/or John Stabile (her Regional Manager) is with her on a "ride-a-long" and pushing the off-label use, she limits her presentation and does not engage in the same tactics as other sales representatives. As a result, we believe that 35 - 50 is likely the norm for those who are refraining from off label marketing.

257. An analysis of Closed Sales for 2013 by Neurology Sales Representatives demonstrates the link or causation between the illegal practices and the submission of false claims. A copy is attached hereto as Exhibit O. The chart contains the 2013 totals of all shipped sales, including Medicaid, Medicaid HMO and Patient Assistance Programs, less all referrals that were denied or withdrawn. Only included those representatives with 5 or more referrals since less than that likely means a representative who started well into the year.

258. The analysis consisted of 87 neurology sales representatives over the 12 Regional Areas accounting for 4,579 net closed sales from the neurology division. The analysis showed the following:

- the average annual referrals by sales representative is 52.

- 18 of the sales representatives had between 50 - 74 referrals which accounted for 983 referrals or approximately 21% of all referrals.

- 10 of the sales representatives had between 75 - 99 referrals which accounted for 868 referrals or approximately 19% of all referrals.

- 8 of the sales representatives had over 100 referrals which accounted for 1,053 referrals or approximately 23% of all referrals.

259. Using these parameters, an error rate of 63% of all neurology referrals are a result of off label marketing, or 2,904 out of the total of 4,579.

260. Similar to the analysis for 2013, an analysis of Closed Sales for 2014 by Neurology Sales Representative further demonstrates the link or causation between the illegal practices and the submission of false claims. A copy is attached hereto as Exhibit P

261. The chart contains the 2014 totals of all shipped sales, including Medicaid, Medicaid HMO and Patient Assistance Programs, less all referrals that were denied or withdrawn. As with the Report in 2013, only those representatives with 5 or more referrals are included since less than that likely means a representative who started well into the year.

262. Based on the foregoing criteria, set forth is an analysis and comparison of the 2013 and 2014 Closed Sales Reports.

263. The 2013 data consisted of 87 neurology sales representatives over the 12 Regional Areas accounting for 4,579 net closed sales from the neurology division.

264. The 2014 data consisted of 107[21] neurology sales representatives over the 12 Regional Areas accounting for 5,063 net closed sales from the neurology division analysis showed the following:

- The average annual referrals by sales representative:

[21] This represents 101 sales representatives and 6 areas that do not have a sales representative assigned but there are reported sales from that area that are included in the gross total of 5,063 total closed sales and are considered when calculated the average annual referrals by sales representative.

2013	52
2014	47

- **Referrals between 50 - 74**

In 2013, 18 of the sales representatives had between 50 - 74 referrals which accounted for 983 referrals or approximately 21% of all referrals.

In 2014, 17 of the sales representatives had between 50 - 74 referrals which accounted for 1,136 referrals or approximately 22% of all referrals.

- **Referrals between 75- 99**

In 2013, there were 10 of the sales representatives who had between 75 - 99 referrals which accounted for 868 referrals or approximately 19% of all referrals.

In 2014, there were 5 of the sales representatives who had between 75 - 99 referrals which accounted for 446 referrals or approximately 9% of all referrals.

- **Referrals over 100**

In 2013, 8 of the sales representatives had over 100 referrals which accounted for 1,053 referrals or approximately 23% of all referrals.

In 2014, 11 of the sales representatives had over 100 referrals which accounted for 1,597 referrals or approximately 32% of all referrals.

Using these parameters, in 2013, we calculated an error rate[22] of 63% of all neurology referrals are a result of off label marketing or illegal inducements, or 2,904 out of the total of 4,579.

265. Using these same parameters, in 2014, the error rate is also 63% of all neurology sales as a result of the off label marketing or illegal inducements, or 3,179 out of a total of 5,063.

XIII. CAUSES OF ACTIONS

A. COUNT ONE

THE FCA: 31 U.S.C. § 3729(a)(1)(A)

266. All of the allegations set forth herein in paragraphs 1 - 265 are incorporated herein by reference as if fully set forth at length.

267. The Defendants knowingly caused to be presented false or fraudulent claims to Government Health Care Programs and knowingly made, used or caused to be made or used, false statements to get said claims paid by Federal Health Care Programs as follows. The Federal FCA, 31 U.S.C. § 3729(a)(1)(A)[23] makes "knowingly"presenting or causing to be presented to the United States any false or

[22] The "error rate" is assumed to be all referrals over the "average" referrals for the sales representative. In 2013, the average was 52, so all sales above 50 were used. In 2014, given that the average referrals were 47, we continued to use the same basis, i.e., all referrals above 50.

[23] On May 22, 2009, the Fraud Enforcement and Recovery Act (FERA) was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered ceratin sections. Under FERA, effective 5/22/09 3729(a)(1) became 3729(A)(1). Likewise, 3729(a)(2) became 3729(A)(2) and 3729(a)(3) became 3729(A)(3) . Since the allegations include a time period before and after 5/22/09, references are to be applicable sections

fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000.

B. COUNT TWO

THE FCA: 31 U.S.C. § 3729(a)(1)(B)

268. All of the allegations set forth herein in paragraphs 1 - 265 are incorporated herein by reference as if fully set forth at length.

269. The Federal FCA, 31 U.S.C. § 3729(a)(1)(B) makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of $5,500 and $11,000.

C. COUNT THREE

THE FCA: 31 U.S.C. § 3729(a)(3)

270. The Federal FCA, 31 U.S.C. sec. 3729(a)(3) makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000.

D. COUNT FOUR

Violations of the California FCA by Defendants

271. Defendants violated the California FCA in the following respects:

a. California Government Code §12651(a)(1) prohibits a person from knowingly presenting or causing to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.

b. California Government Code §12651(a)(2) prohibits a person from knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the state;

c. California Government Code §12651(a)(3) prohibits a person from conspiring to defraud the state by getting a false claim allowed or paid by the state; and

d. California Government Code §12651(a)(7) prohibits a person from knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the state.

E. COUNT FIVE

Violations of the Delaware FCA by Defendants

272. Defendants violated the Delaware FCA in the following respects:

a. The Defendants violated the Delaware FCA §1201(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Delaware a false or fraudulent claim for payment or approval;

b. Defendants violated Delaware FCA §1201(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware;

c. Defendants violated Delaware FCA §1201(a)(3) by conspiring to defraud the State of Delaware by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Delaware FCA §1201(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware.

F. COUNT SIX

Violations of the Florida FCA by Defendants

273. Defendants violated the Florida FCA in the following respects:

a. Defendants violated §68.082(2)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Florida a false or fraudulent claim for payment or approval;

b. Defendants violated §68.082(2)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida;

c. Defendants violated §68.082(2)© by conspiring to defraud the State of Florida by getting a false or fraudulent claim allowed or paid;

d. Defendants violated §68.082(2)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida.

G. COUNT SEVEN

Violations of the Georgia FCA by Defendants

274. Defendants violated the Georgia FCA in the following respects:

a. Defendants violated O.C.G.A. §49-4-168.1(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Georgia a false or fraudulent claim for payment or approval;

b. Defendants violated O.C.G.A. §49-4-168.1(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia;

c. Defendants violated O.C.G.A. §49-4-168.1(a)(3) by conspiring to defraud the State of Georgia by getting a false or fraudulent claim allowed or paid;

d. Defendants violated O.C.G.A. §49-4-168.1(a)(7) by knowingly making,

using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia.

H. COUNT EIGHT

Violations of the Hawaii FCA by Defendants

275. Defendants violated the Hawaii FCA in the following respects:

a. Defendants violated H.R.S. Section 661.21(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval;

b. Defendants violated H.R.S. Section 661.21(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii;

c. Defendants violated H.R.S. Section 661.21(a)(3) by conspiring to defraud the State of Hawaii by getting a false or fraudulent claim allowed or paid;

d. Defendants violated H.R.S. Section 661.21(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii.

I. COUNT NINE

Violations of the Illinois FCA by Defendants

276. Defendants violated the Illinois FCA in the following respects:

a. Defendants violated 740 ILCS 175/3(a)(1)(A) by knowingly presenting or causing to be presented to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval;

b. Defendants violated 740 ILCS 175/3 (a)(1)(B) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois;

c. Defendants violated 740 ILCS 175/3 (a)(1)© by conspiring to commit a violation of subparagraphs (A), (B), or (G);

d. Defendants violated 740 ILCS 175/3 (a)(1)(G) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Illinois.

J. COUNT TEN

Violations of the Indiana FCA by Defendants

277. Defendants violated the Indiana FCA in the following respects:

a. Defendants violated I.C.5-11-5.5-2(b)(1) by knowingly presenting a false claim to the State of Indiana for payment or approval;

b. Defendants violated I.C. 5-11-5.5-2(b)(6) by knowingly making or using a false record or statement to obtain payment or approval of a false claim from the State of Indiana;

c. Defendants violate I.C. 5-11-5.5-2 (b)(6) by making or using a false record or statement to avoid an obligation to pay the State of Indiana.

d. Defendants violated I.C. 5-11-5.5-2 (b)(7) by knowingly conspiring with another person to perform any of those acts described in (a), (b), and © above.

K. COUNT ELEVEN

Violations of the Louisiana FCA by Defendants

278. Defendants violated the Louisiana FCA in the following respects:

a. Defendants violated RS 46:438.3A by knowingly presenting or causing to be presented a false or fraudulent claim;

b. Defendants violated RS 46:438.3B by knowingly engaging in misrepresentation or making, using, or causing to be made or used, a false record or statement to obtain payment for a false or fraudulent claim from the Louisiana Medicaid program;

c. Defendants violated RS 46:438.3C by knowingly making, using, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay money to the Louisiana Medicaid program;

d. Defendants violated RS 46:438.3D by conspiring to defraud, or attempt to defraud, the Louisiana Medicaid program through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

e. Defendants violated RS 46.438.2A(2) by soliciting, receiving, offering, or paying remuneration, including but not limited to kickbacks, bribes, rebates, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, leasing, or ordering, any good, supply, service or facility for which payment may be made, in whole or in part, under the Louisiana Medicaid program.

L. COUNT TWELVE

Violations of the Michigan FCA by Defendants

279. Defendants violated the Michigan FCA in the following respects:

a. Defendants violated MCL 400.607(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Michigan a claim under the social welfare act, upon or against the state, knowing the claim to be false;

b. Defendants violated MCL 400.604 by knowingly soliciting, offering, or receiving a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to a program established under Act No. 280 of the Public Acts of 1939, as amended;

c. Defendants violated MCL 400.606(1) by entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act;

d. Defendants violated MCL 400.607(3) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Michigan pertaining to a claim presented under the social welfare act.

M. COUNT THIRTEEN

Violations of the Montana FCA by Defendant

280. Defendants violated the Montana FCA in the following respects:

a. Defendants violated MCA 17-8-403(1)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Montana a false or fraudulent claim for payment or approval;

b. Defendants violated MCA 17-8-403(1)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana;

c. Defendants violated MCA 17-8-403(1)© by conspiring to commit a violation of subparagraphs (a), (b), or (g);

d. Defendants violated MCA 17-8-403(1)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana.

N. COUNT FOURTEEN

Violations of the Nevada FCA by Defendant

281. Defendants violated the Nevada FCA in the following respects:

a. Defendants violated NRS 357.040(1)(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

b. Defendants violated NRS 357.040(1)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada;

c. Defendants violated NRS 357.040(1)© by conspiring to commit a violation of subparagraphs (a), (b), or (g);

d. Defendants violated NRS 357.040(1)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada.

O. COUNT FIFTEEN

Violations of the New Jersey FCA by Defendant

282. Defendants violated the New Jersey FCA in the following respects:

a. violated the New Jersey FCA §2A:32C-3a by knowingly presenting or causing to be presented to an officer or employee or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

b. Defendants violated New Jersey FCA §2A:32C-3b by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey;

c. Defendants violated New Jersey FCA §2A:32C-3c by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid by the State;

d. Defendants violated New Jersey FCA §2A:32C-3g by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

P. COUNT SIXTEEN

Violations of the New Mexico FCA by Defendant

283. Defendants violated the New Mexico FCA in the following respects:

a. violated NMSA §27-14-4A by presenting or causing to be presented to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;

b. Defendants violated NMSA §27-14-4C by making, using or causing to be made or used a false record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

c. Defendants violated NMSA §27-14-4D by conspiring to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;

d. Defendants violated NMSA §27-14-4E by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State, relative to the Medicaid program, knowing that such record or statement is false.

Q. COUNT SEVENTEEN

Violations of the New York FCA by Defendant

284. The Defendants violated the New York FCA in the following respects:

a. The Defendants violated State Fin. Law §189.1(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;

b. The Defendants violated State Fin. Law §189.1(b) by knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim;

c. The Defendants violated State Fin. Law §189.1© by conspiring to commit a violation paragraph (a), (b) or (g) of this subdivision;

d. The Defendants violated State Fin. Law §189.1(g) by knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state.

R. COUNT EIGHTEEN

Violations of the Oklahoma FCA by Defendant

285. Defendants violated the Oklahoma FCA in the following respects:

a. Defendants violated Okla. Stat. §63-5053.1(B)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

b. Defendants violated Okla. Stat. §63-5053.1(B)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state;

c. Defendants violated Okla. Stat. §63-5053.1(B)(3) by conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Okla. Stat. §63-5053.1(B)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

S. COUNT TWENTY

Violations of the Rhode Island FCA by Defendant

286. Defendants violated the Rhode Island FCA in the following respects:

a. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the state or member of the guard a false or fraudulent claim for payment or approval;

b. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state;

c. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(3) by conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

d. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

T. COUNT TWENTY ONE

Violations of the Tennessee FCA by Defendant

287. Defendants violated the Tennessee FCA in the following respects:

a. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(A) by presenting or causing to be presented to the state a claim under the Medicaid program knowing such claim is false or fraudulent;

b. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(B) by making, using or causing to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid or approved by the state knowing such record or statement is false;

c. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)© by conspiring to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;

d. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(D) by making, using or causing to be made or used, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing such record or statement is false.

U. COUNT TWENTY TWO

Violations of the Texas FCA by Defendant

288. Defendants knowingly or intentionally reported to the State of Texas' Medicaid Program false statements or misrepresentations regarding their

pharmaceutical products. These actions were repeated and continuous violations of the Texas Medicaid Fraud Prevention Act ("TMFPA").

289. Defendants violated the TMFPA in the following respects:

a. Section 36.002(1) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program;

b. Section 36.002(2) prohibits a person from knowingly or intentionally concealing or failing to disclose an event that permits a person to receive a benefit or payment that is not authorized, or that permits a person to receive a benefit or payment that is greater than the benefit or payment that is authorized;

c. Section 36.002(4) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program;

d. Section 36.002(5) prohibits a person, except as authorized under the Medicaid program, from knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or

product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program; and

e. Section 36.002(9) prohibits a person from knowingly entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent.

V. COUNT TWENTY THREE

Violations of the Wisconsin FCA by Defendants

290. Defendants violated the Wisconsin FCA in the following respects:

a. Defendants violated Wis. Stat. §20.931(2)(a) by knowingly presenting or causing to be presented to an officer, employee, or agent of the state a false claim for medical assistance;

b. Defendants violated Wis. Stat. §20.931(2)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false claim paid for medical assistance;

c. Defendants violated Wis. Stat. §20.931(2)© by conspiring to defraud the state by obtaining allowance or payment of a false claim for medical assistance or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program;

d. Defendants violated Wis. Stat. §20.931(2)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

W. COUNT TWENTY FOUR

Violations of the Massachusetts FCA by Defendant

291. Defendants violated the Massachusetts FCA in the following respects:

a. Defendants violated Mass. Gen. Laws Ch. 12, §5B(1) by knowingly presenting or causing to be presented a false claim for payment or approval;

b. Defendants violated Mass. Gen. Laws Ch. 12, §5B(2) by knowingly making, using or causing to be made or used a false record or statement to obtain payment or approval of a claim by the commonwealth;

c. Defendants violated Mass. Gen. Laws Ch. 12, §5B(3) by conspiring to defraud the commonwealth through the allowance or payment of a fraudulent claim;

d. Defendants violated Mass. Gen. Laws Ch. 12, §5B(8) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the commonwealth.

X. COUNT TWENTY FIVE

Violations of the Virginia FCA by Defendants

292. Defendants violated the Virginia FCA in the following respects:

a. Defendants violated Code of Virginia § 8.01-216.3A(1) by knowingly presenting, or causing to be presented, to an officer or employee of the Commonwealth a false claim for payment or approval;

b. Defendants violated Code of Virginia § 8.01-216.3A(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

c. Defendants violated Code of Virginia § 8.01-216.3A(3) by conspiring to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Code of Virginia § 8.01-216.3A(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

Y. COUNT TWENTY SIX

Violations of the District of Columbia FCA by Defendants

293. Defendants violated the District of Columbia FCA in the following respects:

a. Defendants violated D.C. Code Ann., 2-308.14(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the District a false claim for payment or approval;

b. Defendants violated D.C. Code Ann., 2-308.14(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or approved by the District;

c. Defendants violated D.C. Code Ann., 2-308.14(a)(3) by conspiring to defraud the District by getting a false claim allowed or paid by the District;

d. Defendants violated D.C. Code Ann., 2-308.14(a)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District.

Z. COUNT TWENTY SEVEN

Violations of the Chicago FCA by Defendants

294. Defendants violated the Chicago FCA in the following respects:

a. Defendants violated Mun. Code of Chicago 1-22-020(1) by knowingly presenting, or causing to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval;

b. Defendants violated Mun. Code of Chicago 1-22-020(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District;

c. Defendants violated Mun. Code of Chicago 1-22-020(3) by conspiring to defraud the District by getting a false claim allowed or paid by the city;

d. Defendants violated Mun. Code of Chicago 1-22-020(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the city.

AA. COUNT TWENTY EIGHTH

Violations of the Connecticut FCA by Defendants

295. Defendants violated the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301 through 17b-301p ("Connecticut FCA") in the following respects:

a. Defendants violated the Connecticut FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Connecticut FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated the Connecticut FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Connecticut FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

BB. COUNT TWENTY NINTH

Violations of the Maryland FCA by Defendants

296. Defendants violated the Maryland Health False Claims ACT, as amended by Maryland Laws Ch 66. Title 2, Subchapter 6, § 2-601 to § 2-610 ("Maryland FCA") in the following respects:

a. Defendants violated the Maryland FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Maryland FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated the Maryland FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Maryland FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

CC. COUNT THIRTIETH

Violations of the Washington FCA by Defendants

297. Defendants violated the Washington Medicaid Fraud False Claims Act, WASH. SESS. LAWS, LAWS OF 2012, ch. 241 §§ 201 through 214 ("Washington FCA") in the following respects:

a. Defendants violated the Washington FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Washington FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated the Washington FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Washington FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

DD. COUNT THIRTY FIRST

Violations of the Colorado FCA by Defendants

298. Defendants violated the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310 ("Colorado FCA") in the following respects:

a. Defendants violated, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Colorado FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated Colorado FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated Colorado FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

EE. COUNT THIRTY SECOND

Violations of the Iowa FCA by Defendants

299. Defendants violated the Iowa False Claims Act ("Iowa FCA") Iowa Code §§ 685.1 through 685.7 in the following respects:

a. Defendants violated Iowa FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

b. Defendants violated the Iowa FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

c. Defendants violated Iowa FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;

d. Defendants violated the Iowa FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

FF. COUNT THIRTY THIRD

Pratta, individually under the under the New Jersey Conscientious Employee Protection Act N. J. Stat. Ann. § 34:19-1 et. seq. ("CEPA") v Defendants.

300. All of the allegations set forth herein in paragraphs 1 - 265 are incorporated herein by reference as if fully set forth at length.

301. Pratta had a reasonable and good faith belief that the actions described herein, specifically in ¶ 104 to ¶ 228 and ¶ 232 to ¶ 255 in were illegal and/or violative of a law, rule or regulation. As an example, Pratta became aware and observed numerous serious compliance issues and concerns relating to Patrick Sullivan and others, including, inter alia, Report Number MLCK-16-12-002, (*violation of policy prohibiting sales representative from being with head pharmacist of medical facility*) all of which she reported in August 2016 to Angie Woods, HR Director.

302. Pratta's disclosures to her supervisory personnel of the policies described herein and refusal to participate in the activities, policies or practices of Defendant which she felt were fraudulent and violative of law and/or criminal were protected pursuant to the provisions of N.J.S.A. 34:19-3(a) and (c)(1), (2) and (3).

303. The actions of Defendant in terminating the employment of Pratta and otherwise adversely affecting Pratta's employment as set fort herein were in retaliation for Pratta's complaints and objections and/or refusal to participate in activities, polices and practices of Defendant which Pratta reasonably believed to be fraudulent and violative of law and/or criminal, which have been set forth at length herein.

304. In order to succeed on a claim under the New Jersey Conscientious Employee Protection Act ("CEPA"), N.J.S.A. 34:19-1, et seq., and more specifically, 34:19-3(a) and/or ©, a Plaintiff must show the following

(i) she *reasonably believed* that an activity, policy or practice of her employer was in violation of a law, rule or regulation promulgated pursuant to law, or was fraudulent or criminal, or was incompatible with a clear mandate of public policy concerning the public health, safety, or welfare or protection of the environment.

(ii) she objected to, complained about, or refused to participate in, the activity, policy or practice; or reported the wrong doing to an appropriate enforcement authority

(iii) retaliatory action was taken against her (i.e., an adverse employment action occurred); and

(iv) there was a causal connection between the Plaintiff's action and the retaliatory or adverse action of the employer.

305. Pratta went on disability January 11,2016 until June 2th 2016 and then again went out again on December 20,2016 as a result of knee surgeries.

306. Shortly thereafter, Pratta was terminated because she was allegedly a "low performer" based on the result of a company wide review to reduce the neurology sales force based on performance. Out of 84 neurology sales representatives, 7 were laid off which presumably represented the bottom tier of those representatives who did not achieve their respective goals, claiming that she only met 47.8% of her goal during this period and, based on her comparable results with others, her position was selected for termination. The selected period of review were the five quarters beginning with the last two quarters of 2015 and the first three quarters of 2016.

307. Even though she was on medical leave, Pratta followed through on all her referrals and her offices. Based on the 5 quarters that were used in the analysis, Pratta was at 58.1% to goal. Despite the fact that Ms Pratta provided objective quantifiable evidence that the company's calculations were in error and that she had achieved 58.1% of her goal, placing her at 59 out of 84 in terms of performance, Company refused to re-consider it's decision to terminate her employment.

WHEREFORE, the Pratta demands judgment against Defendant for:

(a) Any and all remedies available under the New Jersey CEPA;

(b) An Award of compensatory damages for injuries including emotional distress and physical anguish, suffered as a result of Defendant's violations of a New Jersey law against discrimination;

(c) Punitive damages;

(d) Attorney's fees and costs incurred by the need to bring this litigation pursuant to the fee shifting provisions of the New Jersey CEPA;

(e) Pre and post judgment interest;

(f) Any and all damages actually incurred by plaintiff, including actual, consequential and special damages; and

(g) Such other relief as the Court may deem equitable and just.

GG. COUNT THIRTY FOURTH

Pratta, individually under the under the New Jersey Law Against Discrimination Act N. J. Stat. Ann. N.J.S.A. 10:5-12 ("LAD") v Defendants

308. All of the allegations set forth herein in paragraphs 1 - 307 are incorporated herein by reference as if fully set forth at length.

309. Pratta went on disability January 11,2016 until June 2th 2016 and then again went out again on December 20,2016 as a result of knee surgeries. As a result she was disabled.

310. Pratta became aware and observed numerous serious compliance issues and concerns relating to Patrick Sullivan and others, including, inter alia, harassment regarding her disability and Report Number MLCK-16-12-002, (*violation of policy prohibiting sales representative from being with head*

pharmacist of medical facility) all of which she reported in August 2016 to Angie Woods, HR Director.

311. Pratta's disclosures that she was being discriminated against as result of her disability violates the LAD which makes it unlawful to subject people to differential treatment based on inter alia,race, creed, color, national origin, nationality, ancestry, age, sex (including pregnancy), familial status, marital status, domestic partnership or civil union status, and disability.

312. Shortly thereafter, Pratta was terminated because she was allegedly a "low performer" based on the result of a company wide review to reduce the neurology sales force based on performance.

WHEREFORE, the Pratta demands judgment against Defendant for:

(a) Any and all remedies available under the New Jersey LAD;

(b) An Award of compensatory damages for injuries including emotional distress and physical anguish, suffered as a result of Defendant's violations of the LAD;

© Punitive damages;

(d) Attorney's fees and costs incurred by the need to bring this litigation pursuant to the fee shifting provisions of the New Jersey law against discrimination;

(e) Pre and post judgment interest;

(f) Any and all damages actually incurred by plaintiff, including actual, consequential and special damages; and

(g) Such other relief as the Court may deem equitable and just.

XIV. DAMAGES

313. The measure of damages the United States is entitled to recover under the FCA is the amount of money the government paid out by reason of the false claims over and above what it would have paid out if the claims had not been false or fraudulent. *Marcus,* 317 U.S. at 543-545, 63 S.Ct. 379; *United States v. Neifert-White,* 390 U.S. at 232, 88 S.Ct. 959. The government is allowed to recover three times the amount of its damages. 31 U.S.C. § 3729(a). "FCA damages 'typically are liberally calculated to ensure that they afford the government complete indemnity for the injuries done it.' " *United States ex rel. Roby v. Boeing Co.,* 302 F.3d 637, 646 (6th Cir.2002) (quoting *United States ex rel. Compton v. Midwest Specialties, Inc.,* 142 F.3d 296, 304 (6th Cir.1998)).

314. The computation of damages does not have to be done with mathematical precision but, rather, may be based upon a reasonable estimate of the loss.

315. The government is entitled to recover a civil penalty for each false claim. Each knowing submission of a false or fraudulent claim is a separate violation of the False Claims Act. 31 U.S.C. § 3729(a)(2). Thus, the number of violations of the False Claims Act depends on the number of false or fraudulent

claims or other requests for payments that defendant caused to be submitted. A penalty is assessed per false claim. *See United States v. Bornstein,* 423 U.S. 303, 313, 96 S.Ct. 523, 46 L.Ed.2d 514 (1976); *United States v. Killough,* 848 F.2d 1523, 1533 (11th Cir.1988) (holding that each separate fraudulent submission by a defendant demanding payment by the government.

316. The penalty is mandatory. See United States v. Hughes, 585 F.2d 284, 286 (7th Cir.1978); *Killough,* 848 F.2d at 1533-34. As the legislative history to the 1986 Amendments to the FCA explains:

> The imposition of this forfeiture is automatic and mandatory for each claim which is found to be false. The United States is entitled to recover such forfeiture solely upon proof that false claims were made, without proof of any damages.... A forfeiture may be recovered from one who submits a false claim even though no payments were made on the claim. S.Rep. No. 345, 99th Cong., 2d Sess. at 8 (July 28, 1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273 (internal citation omitted).

317. The United States does not need to prove actual damages in order to recover these statutory penalties. The United States may recover penalties upon a showing that the claims were false, even if no damage is proved. *Varljen v. Cleveland Gear Co., Inc.,* 250 F.3d 426, 429 (6th Cir.2001) ("recovery under the FCA is not dependent upon the Government's sustaining monetary damages"); *see also United States ex rel. Hagood v. Sonoma County Water Agency,* 929 F.2d 1416, 1421 (9th Cir.1991) ("No damages need be shown in order to recover the penalty") (citing *721 *Rex Trailer Co. v. United States,* 350 U.S. 148, 153 n. 5, 76 S.Ct. 219, 100 L.Ed. 149 (1956).

XV. RELIEF REQUESTED

318. Relator requests the following relief be imposed against Defendants:

(a) That the United States be awarded three times the amount of damages which it sustained because of the acts of Defendants pursuant to §3729(a)(1)(2) and (3) of the FCA;

(b) That Defendants each be held liable for civil penalties of up to $21,563.00, but not less than $10,781.00 (as adjusted pursuant to §3729 of the FCA and the Civil Penalties Act), to the U.S. for each and every act in violation of the FCA; that the Defendants each be held liable for civil penalties applicable for each and every unlawful act in violation of each respective State FCA;

(c) That this Court award such interest as is available pursuant to the FCA;

(d) That in the event the United States intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(1) of the FCA;

(e) That in the event the United States and State Plaintiffs do not intervene in this action, the Relator be awarded an amount for bringing this action for the United States of at least 25% but not more than 30% of the proceeds paid to the

United States resulting from the trial or settlement of the claim, pursuant to §3730(d)(2) of the FCA;

(f) That this Court award reasonable attorneys' fees, costs and expenses to the Relator, which were necessarily incurred in bringing and prosecuting this case, pursuant to §3730(d)(1) or (2) of the FCA ; and

(g) That this Court award such other relief as it deems just, necessary and fair.

JURY DEMAND

Relators requests a trial by jury of all issues so triable.

DATED: June 8, 2017

Respectfully submitted,
Counsel for Plaintiff/Relator

Marc M. Orlow, Esquire
Ross Begelman, Esquire

CERTIFICATION OF SERVICE

Marc Orlow, Esquire, of full age, hereby certify that on June 8, 2017, I filed Relator's Motion to File a Fourth Amended Qui Tam Complaint, Proposed Form of Order in Support of Motion and Relator's Fourth Amended Qui Tam Complaint attached to the Motion to be Filed upon Court's approval in the United States District Court for the Eastern District of Pennsylvania and caused it to be served upon:

Colin Cherico, Esq.
Assistant U.S. Attorney
U.S. Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

Augustine Ripa, Esq.
U.S. Department of Justice
601 D Street, N.W.
Patrick Henry Builiding, Room 1209
Washington, DC 20004

Attached Service List of State Plaintiffs

by Certified Return Receipt Requested to the above listed people.

I certify that the foregoing statements made by me are true. I am aware if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

BEGELMAN & ORLOW

By: _____

Marc Orlow, Esquire

Date: June 8, 2017

List of Exhibits for Fourth Amended Complaint

Exhibit A	FDA Label
Exhibit B	Questcor/Nasdaq March 2011
Exhibit C	BROD Plan
Exhibit D	Questcor Power Point
Exhibit E	Achtar Speaker Training
Exhibit F	Questcor Employee Comparative Study
Exhibit G	MIRF
Exhibit H	Referral Form
Exhibit I	New Referral Form
Exhibit J	Abstract-AAN Meeting
Exhibit K	Provider Profile
Exhibit L	List of Speakers
Exhibit M	Stabile Text Message
Exhibit N	Free Vial E-Mail Re: Katz
Exhibit O	2013 Closed Sales Analysis
Exhibit P	2014 Closed Sales Analysis

List of Exhibits for Fourth Amended Complaint

Exhibit A	FDA Label
Exhibit B	Questcor/Nasdaq March 2011
Exhibit C	BROD Plan
Exhibit D	Questcor Power Point
Exhibit E	Achtar Speaker Training
Exhibit F	Questcor Employee Comparative Study
Exhibit G	MIRF
Exhibit H	Referral Form
Exhibit I	New Referral Form
Exhibit J	Abstract-AAN Meeting
Exhibit K	Provider Profile
Exhibit L	List of Speakers
Exhibit M	Stabile Text Message
Exhibit N	Free Vial E-Mail Re: Katz
Exhibit O	2013 Closed Sales Analysis
Exhibit P	2014 Closed Sales Analysis